

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6)] Jansen, Kathrin [(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6)] Biggs, Mary [(b) (6)] Butcher, Tina [(b) (6)] Demarcus [(b) (6)] Macone, Erin [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6)] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [(b) (6)] Tolman, Brett [(b) (6)] Alvarez, Rosa [(b) (6)] Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6)] Rose Li Central Account [(b) (6)] Anderson, Margaret [(b) (6)] Lucas Smalldon [(b) (6)] Stratton, Benjamin [(b) (6)] [(b) (6)] Mollica, Linda /US [(b) (6)] Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [(b) (6)] Wung, Peter /US [(b) (6)] Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]

Subject: Initial Follow-up to ACTIV TX-Clinical Working Group Meeting #9

Dear ACTIV TX-Clinical WG,

Thank you all for the good discussion and feedback on the master protocols on today's call.

As promised as part of my initial follow up to the meeting, please find below the now active link for agent survey submissions.

<https://redcap.ncats.nih.gov/redcap/surveys/index.php?s=DAE87WPTE7&>

Please feel free to use this for any agents your companies may wish to have considered or share it with any other colleagues who think may have something interesting for us to consider.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/29/2020 12:49:52 AM
To: Garner, Carlos [(b) (6)] Bascles, Lionel [(b) (6)] Vincent, Mike [(b) (6)] Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Cohen, Myron [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)] Victoria Davey [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6)] Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura [(b) (6)] Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6)] Stein, Peter (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wachtel, Jonathan [(b) (6)] Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Kublin MD, MPH, James [(b) (6)] Ferguson, Sue [(b) (6)] Kenny, Dermot [(b) (6)] Gonzalez, Nina [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Criffield, Robin [(b) (6)] Hamilton, Nancy [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [(b) (6)]; Mueller-Reichenstein, Petra [(b) (6)] Quadros, Nora [(b) (6)] Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [(b) (6)] Heaton, Penny [(b) (6)] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6)] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine

From: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
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To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aebc9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Colvis, Christine
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
 [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson
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 [(b) (6) Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Connelly, Sarah
 [(b) (6) Gonzalez, Nina [(b) (6) Hawk, Harrison [(b) (6)
 Mendelson, Jesse [(b) (6) Nasr, Hana [(b) (6) Sorosa, Alex
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 [(b) (6) btolman [(b) (6)]; Wachtel, Jonathan [(b) (6)]; Embry,
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 [(b) (6) Bancel, Stephane [(b) (6)
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 [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Paul, Steve [(b) (6) Rachel Ramoni
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 [(b) (6)
 Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Burrus-Shaw, Cyndi
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 Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
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 Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Lever, Susan

CC:

[(b) (6) Magbie-Robinson, Kim (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74a5b9cea10b4f919d9db20c8aaec3e7-magbierobin]; Martin, Melisa [(b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Riffin, Mary [(b) (6) Ripley, Nadege [(b) (6) Schuster, Donna [(b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy [(b) (6) Zottoli, Jessica [(b) (6) Regan, Donna M [(b) (6) Vessey, Rupert [(b) (6) Burke, Leslie [(b) (6) John Lepore [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Grant, Sarah [(b) (6) Pruitt, Kim (NIH/NLM/NCBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5f43fb8970c343a38150ec1186a34f9a-pruitt]; Sherry, Steve (NIH/NLM/NCBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3339a3f0862046b78f97a029c4753bf3-sherry]; Bell, Julie [(b) (6)]

Subject: ACTIV Leadership Team Call #14

Location: <https://fnih.zoom.us/> [(b) (6)]

Start: 3/18/2021 2:30:00 PM

End: 3/18/2021 4:00:00 PM

Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Young, John; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Meltzer, Abbey (FNIH) [T]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Embry, Alan (NIH/NIAID) [E]; Venkayya, Rajeev; [(b) (6)]

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [E]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C];

Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melisa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riffin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRG) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Hughes, Karen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Regan, Donna M; Vessey, Rupert; Burke, Leslie; John Lepore; Lowy, Douglas (NIH/NCI) [E]; Grant, Sarah; Pruitt, Kim (NIH/NLM/NCBI) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Sent: 5/30/2020 1:01:39 AM
To: Gonzalez, Nina [(b) (6)]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Elsaid, Olivia [(b) (6)]
Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30
Attachments: ACTIV Therapeutics_053020.pptx

Hi all,

Thanks, this is an excellent set, though to keep the discussions with Moncef concise, I've moved some of the slides to the Appendix. See current version. I will send this to Janet now too.

One question: when the immunomodulator slide 7 says this:

All 3 agents have initial Phase II data or are currently running company-sponsored Phase II trials

What does that mean? Phase II trials for what application?

Francis

From: Gonzalez, Nina < (b) (6) >
Sent: Friday, May 29, 2020 8:37 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Cc: Adam, Stacey (FNIH) [T] < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Freire, Maria (FNIH) [T] < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) > Elsaid, Olivia < (b) (6) >
Subject: RE: Key messages immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi Francis,

See attached the latest version of the slides for the meeting tomorrow.

We'll be on standby for any edits you may have.

Thank you,

Nina

Nina Gonzalez
Deloitte Consulting LLP
Tel/Direct (b) (6)
(b) (6) | www.deloitte.com

COLL0000009631-2515101

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Friday, May 29, 2020 8:32 PM
To: Wholley, David (FNIH) [T] (b) (6)
Cc: Adam, Stacey (FNIH) [T] (b) (6); Freire, Maria (FNIH) [T] (b) (6); Gonzalez, Nina (b) (6); Parker, Ashley (NIH/OD) [E] (b) (6) >
Subject: [EXT] RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hoping these are coming to me soon, as I may want to do some editing -- and then I wanted to run them past Janet tonight.

FC

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Friday, May 29, 2020 7:41 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Adam, Stacey (FNIH) [T] (b) (6); Freire, Maria (FNIH) [T] (b) (6) >; Gonzalez, Nina (b) (6); Parker, Ashley (NIH/OD) [E] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)>
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Have seen and offered a few changes to the complete slide deck. They should be coming back to you as soon as Deloitte makes the changes.

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Friday, May 29, 2020 5:59 PM
To: Wholley, David (FNIH) [T] (b) (6)
Cc: Adam, Stacey (FNIH) [T] (b) (6) >; Freire, Maria (FNIH) [T] (b) (6); Gonzalez, Nina <(b) (6)> Parker, Ashley (NIH/OD) [E] (b) (6) >
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note -- has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Friday, May 29, 2020 1:59 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Adam, Stacey (FNIH) [T] (b) (6); Freire, Maria (FNIH) [T] (b) (6); Gonzalez, Nina (b) (6); Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomatology.
 - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
 - ACTIV hiVIG (sponsored by NIAID) – in progress
 - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
 - ACTIV-2* – Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
 - ACTIV-3* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
 - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) – (Phase II/III) – projected launch late June
 - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August (*if needed; i.e. if agents are not incorporated into mAb protocols*)
 - * current priority

[for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
[Key Criteria for Scoring (slide 15 from 5/20) can go to backup]
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
 - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
 - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
 - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
 - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
 - Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
 - Protocol is 80% complete

- Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
 - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
- All three companies have written their sections of the protocols, which are being merged into the master design
 - Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- “ACTIV-4” Protocol for anticoagulants
 - Need bullets from NHLBI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley
 Senior Vice-President, Research Partnerships
 Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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v.E.1

From: Prabha Fernandes (b) (6)
Sent: 6/22/2020 2:41:46 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6) 'Rao, Srinivas' (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; 'Tomas Cihlar' [(b) (6) 'Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)' (b) (6) ; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; 'Diamond, Michael' [(b) (6) Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; 'Baric, Toni C' [(b) (6) 'Rodriguez, Robin D' [(b) (6) 'Hughes, Eric' [(b) (6)]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; 'Desrosiers, Betsy' [(b) (6) 'Jansen, Kathrin' [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T]

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[(b) (6) 'Kim, Elizabeth' [(b) (6) 'Tolman, Brett' [(b) (6)
'Wachtel, Jonathan' (b) (6) 'Prabhavathi Fernandes' [(b) (6) 'Rose Li'
[(b) (6) 'Dana Carluccio' [(b) (6) Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; 'Dave Frankowski'
(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy
Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; 'Stratton, Benjamin'
[(b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

Subject: RE: ACTIV Preclinical full working group

Attachments: ACE2 MiceECONOMIST.doc; MUse ACE2 model Wang Cell host Microbe May 2020.pdf

Dear Joe and Animal model WG,

I read in Economist and then pulled down the paper..do we have mice with the right ACE2 construct for use?

Regards,

Prabha

From: Menetski, Joseph (FNIH) [T] < (b) (6) >

Sent: Monday, June 22, 2020 9:53 AM

To: (b) (6) (b) (6) (b) (6) Rao, Srinivas

< (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] < (b) (6) >

(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)

Baric, Ralph < (b) (6) (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E]

< (b) (6) Colvis, Christine (NIH/NCATS) [E] < (b) (6) Hewitt, Judith (NIH/NIAID)

[E] < (b) (6) Deming, Damon (FDA/CDER) < (b) (6) (b) (6)

(b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) (b) (6) Adams,

Peter (OS/ASPR/BARDA) < (b) (6) Qashu, Felicia (NIH/OD) [E] < (b) (6) Tomas Cihlar

< (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) < (b) (6)

Punturieri, Antonello (NIH/NHLBI) [E] < (b) (6) Charette, Marc (NIH/NHLBI) [E]

< (b) (6) Fessel, Josh (NIH/NHLBI) [E] < (b) (6)

Cc: Culp, Michelle (NIH/OD) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6)

Diamond, Michael < (b) (6) Nancy Haigwood < (b) (6) Baric, Toni C

< (b) (6) Rodriguez, Robin D < (b) (6) Hughes, Eric

< (b) (6) Florence, Clint (NIH/NIAID) [E] < (b) (6) Wholley, David (FNIH) [T]

< (b) (6) Austin, Christopher (NIH/NCATS) [E] < (b) (6) Melencio, Cheryl (FNIH) [T]

< (b) (6) Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy

< (b) (6) Jansen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E]

< (b) (6) Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6)

Tountas, Karen (FNIH) [T] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T]

< (b) (6) James, Stephanie (FNIH) [T] < (b) (6) Alvarez, Rosa Maria < (b) (6)
Kim, Elizabeth < (b) (6) Tolman, Brett < (b) (6) Wachtel, Jonathan
< (b) (6) Prabhavathi Fernandes < (b) (6) Rose Li
< (b) (6) Dana Carluccio < (b) (6) Lagos, Enrique (NIH/NCATS) [E]
< (b) (6) Jonson, Samantha (NIH/NCATS) [E] < (b) (6) Gonzalez, Nina
< (b) (6) Simon, Dina (NIH/OD) [C] < (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E]
< (b) (6) Dave Frankowski < (b) (6) Lowy, Douglas (NIH/NCI) [E]
< (b) (6) Nancy Haigwood < (b) (6) Stratton, Benjamin < (b) (6)
Anderson, James (NIH/OD) [E] < (b) (6)

Subject: RE: ACTIV Preclinical full working group

Dear Preclinical Working group members and invitees,

Please review the minutes from the last full meeting of the working group. If you have any questions, or we missed anything, let me know.

Best regards,

Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

To: (b) (6) (b) (6) (b) (6) Rao, Srinivas;

(b) (6) Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6);

(b) (6)

(b) (6) (b) (6); (b) (6)

(b) (6) (b) (6); (b) (6) Parker, Ashley (NIH/OD) [E]; Collins,

Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Qashu, Felicia (NIH/OD) [E];
Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette,
Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]

Cc: Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Diamond, Michael; Nancy Haigwood; Baric, Toni C;
Rodriguez, Robin D; Hughes, Eric; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Austin, Christopher
(NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin;
Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos,
Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman,
Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson,
Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Dave
Frankowski; Lowy, Douglas (NIH/NCI) [E]; Nancy Haigwood; Stratton, Benjamin; Anderson, James (NIH/OD) [E]

Subject: ACTIV Preclinical full working group

When: Wednesday, June 17, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: [https://fnih.zoom.us/j/\(b\) \(6\)](https://fnih.zoom.us/j/(b) (6))

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

[https://fnih.zoom.us/j/\(b\) \(6\)](https://fnih.zoom.us/j/(b) (6))

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Password: (b) (6)

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US (Germantown)

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US (Germantown)

US (Chicago)

US (New York)

US (San Jose)

US (San Jose)

US (Tacoma)

US (Houston)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/> (b) (6)

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 12/18/2020 5:11:10 PM
To: Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbef0ffb5e52c31a4-tuckerjm]
Subject: RE: ACTIV slides from today on escape mutations

And more from the FNIH/Deloitte call—Moncef Slaoui is going to ask BARDA for the funds for this project. FNIH is prepping a budget.

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Friday, December 18, 2020 10:41 AM
To: Tucker, Jessica (NIH/OD) [E] <(b) (6)>
Subject: RE: ACTIV slides from today on escape mutations

More today on the ACTIV preclinical WG call: FYI this whole effort also includes escape mutants from the vaccines, not just the therapeutics. And I think the member from Roche said something like there are already mutations known to affect efficacy of cocktails (presumably of antibodies), but I am not sure I heard that right. At any rate, I keep hearing the FDA is requiring companies to generate this information.

From: Tucker, Jessica (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, December 16, 2020 4:17 PM
To: Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Subject: RE: ACTIV slides from today on escape mutations

Thank you!

From: Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, December 16, 2020 1:16 PM
To: Tucker, Jessica (NIH/OD) [E] <(b) (6)>
Subject: FYI: ACTIV slides from today on escape mutations

See slides 6-10. Note that slide 8 includes “selection screens.” There was general enthusiasm on the call today for the general effort and FC asked industry members what they could do to help. Skip Virgin from VIR said that there are certain experiments that FDA is also asking sponsors to conduct and so centralizing assays and information was important. There was then discussion of a platform that FDA/BARDA/OWS has apparently already built that takes sequence data, makes pseudotype viruses, and run them against a panel of antibodies. (I had to look up pseudotyping—it sounds like it is making a replication incompetent virus.) Not much more detail.

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> > On Behalf Of Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 6:29 PM
To: Wholley, David (FNIH) [T] <(b) (6)>; Austin, Christopher (NIH/NCATS) [E] <(b) (6)>; Bancel, Stephane <(b) (6)>; Carter, Kara <(b) (6)>; Cavaleri, Marco <(b) (6)>; Cihlar, Tomas <(b) (6)>; Collins, Francis (NIH/OD) [E] <(b) (6)>; Corey, Larry <(b) (6)>; Culp, Michelle (NIH/OD) [E] <(b) (6)>; Victoria Davey <(b) (6)>; Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>; Dolsten, Mikael <(b) (6)>; Erbeling, Emily (NIH/NIAID) [E] <(b) (6)>; Erck, Stan <(b) (6)>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>; Freire, Maria (FNIH) [T] <(b) (6)>; Gadbois, Ellen (NIH/OD) [E] <(b) (6)>; Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)>; Hudson, Thomas <(b) (6)>; James, Stephanie (FNIH) [T]

< (b) (6) : Johnson, Robert (OS/ASPR/BARDA) (b) (6) >; Kramer, Lynn
 (b) (6) : Lane, Cliff (NIH/NIAID) [E] (b) (6) : Lepore, John (b) (6) >;
 Marks, Peter (FDA/CBER) < (b) (6) : Marston, Hilary (NIH/NIAID) [E] (b) (6) >;
 Mascola, John (NIH/VRC) [E] (b) (6) : Meeker, David (b) (6) >; Menetski, Joseph
 (FNIH) [T] (b) (6) >; Messonnier, Nancy (CDC/DDID/NCIRD/OD) < (b) (6) : Pandya, Hitesh
 (b) (6) >; Pangalos, Mene (b) (6) : Pao, William
 < (b) (6) : Parker, Ashley (NIH/OD) [E] (b) (6) : Paul, Steve (b) (6) >;
 Perlmutter, Roger (b) (6) >; Plenge, Robert < (b) (6) : Plump, Andy
 < (b) (6) : Rachel Ramoni (b) (6) : Reed, John (b) (6) >; Reese,
 David < (b) (6) >; Rouse, Doris (b) (6) : Santos, Michael (FNIH) [T] < (b) (6)
 Skovronsky, Daniel (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) : Stoffels, Paul
 < (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) : Talley, Michael
 (b) (6) : Tsai, John (b) (6) >; Vessey, Rupert (b) (6) : Virgin, Skip
 (b) (6) : Woodcock, Janet (FDA/CDER) < (b) (6) : Young, John
 (b) (6) >; Colvis, Christine (NIH/NCATS) [E] < (b) (6) >; Desrosiers, Betsy
 (b) (6) >; Eric Hughes (b) (6) >; Jansen, Kathrin
 (b) (6) >; Kurilla, Michael (NIH/NCATS) [E] (b) (6) >; Lowy, Douglas (NCI)
 < (b) (6) : Read, Sarah (NIH/NIAID) [E] < (b) (6) : Young, John < (b) (6) >;
 Adam, Stacey (FNIH) [T] (b) (6) : Margaret Anderson (b) (6) >; Appell, Evan
 (b) (6) : Chen, Helen Q. < (b) (6) >; Connelly, Sarah (b) (6)
 Gonzalez, Nina (b) (6) >; Hawk, Harrison < (b) (6) : Mendelson, Jesse
 (b) (6) >; Menetski, Joseph (FNIH) [T] (b) (6) >; Nasr, Hana (b) (6) >;
 Santos, Michael (FNIH) [T] (b) (6) >; Sorosa, Alex David (b) (6) : Stratton, Benjamin
 < (b) (6) : btolman < (b) (6) >; Tountas, Karen (FNIH) [T] (b) (6)
 Wachtel, Jonathan (b) (6)
Cc: Anderson, James (NIH/OD) [E] < (b) (6) >; Austin, Christopher (NIH/NCATS) [E]
 (b) (6) >; Burklow, John (NIH/OD) [E] < (b) (6) : Carluccio, Dana
 (b) (6) : Castillejos, Carlos (b) (6) >; FNIH Central Account
 (b) (6) >; Hallett, Adrienne (NIH/OD) [E] (b) (6) >; Lane, Cliff (NIH/NIAID) [E]
 (b) (6) : Myles, Renate (NIH/OD) [E] (b) (6) : Parker, Ashley (NIH/OD) [E]
 (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Wolinetz, Carrie (NIH/OD) [E]
 (b) (6) >; Meltzer, Abbey (FNIH) [T] (b) (6)

Subject: RE: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION

Dear ACTIV Leadership Team and meeting attendees:

Please see corrected version of materials. Sorry for the confusion.

Regards,

David

David Wholley
 Senior Vice-President, Research Partnerships
 Foundation for the National Institutes of Health
 (b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] (b) (6) > **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 5:08 PM
To: Austin, Christopher (NIH/NCATS) [E] (b) (6) ; Bancel, Stephane
 (b) (6) >; Carter, Kara (b) (6) >; Cavaleri, Marco
 (b) (6) >; Cihlar, Tomas (b) (6) >; Collins, Francis (NIH/OD) [E]
 (b) (6) Corey, Larry (b) (6) >; Culp, Michelle (NIH/OD) [E] < (b) (6)
 Victoria Davey < (b) (6) ; Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) ; Dolsten, Mikael
 (b) (6) >; Erbelding, Emily (NIH/NIAID) [E] (b) (6) ; Erck, Stan
 (b) (6) >; Fauci, Anthony (NIH/NIAID) [E] < (b) (6) Freire, Maria (FNIH) [T]
 < (b) (6) ; Gadbois, Ellen (NIH/OD) [E] (b) (6) ; Gibbons, Gary (NIH/NHLBI) [E]
 (b) (6) >; Hudson, Thomas < (b) (6) ; James, Stephanie (FNIH) [T]
 (b) (6) ; Johnson, Robert (OS/ASPR/BARDA) (b) (6) >; Kramer, Lynn
 (b) (6) ; Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Lepore, John < (b) (6)
 Marks, Peter (FDA/CBER) < (b) (6) ; Marston, Hilary (NIH/NIAID) [E] (b) (6) >;
 Mascola, John (NIH/VRC) [E] < (b) (6) ; Meeker, David (b) (6) ; Menetski, Joseph
 (FNIH) [T] (b) (6) ; Messonnier, Nancy (CDC/DDID/NCIRD/OD) < (b) (6) >; Pandya, Hitesh
 (b) (6) ; Pangalos, Mene (b) (6) >; Pao, William
 < (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) ; Paul, Steve < (b) (6)
 Perlmutter, Roger (b) (6) ; Plenge, Robert (b) (6) ; Plump, Andy
 (b) (6) >; Rachel Ramoni (b) (6) ; Reed, John < (b) (6) >; Reese,
 David < (b) (6) >; Rouse, Doris (b) (6) ; Santos, Michael (FNIH) [T] (b) (6)
 Skovronsky, Daniel (b) (6) ; Stein, Peter (FDA/CDER) (b) (6) >; Stoffels, Paul
 (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Talley, Michael
 < (b) (6) ; Tsai, John < (b) (6) >; Vessey, Rupert (b) (6) ; Virgin, Skip
 < (b) (6) Wholley, David (FNIH) [T] (b) (6) >; Woodcock, Janet (FDA/CDER)
 (b) (6) >; Young, John (b) (6) ; Colvis, Christine (NIH/NCATS) [E]
 (b) (6) ; Desrosiers, Betsy < (b) (6) >; Eric Hughes
 (b) (6) >; Jansen, Kathrin < (b) (6) ; Kurilla, Michael (NIH/NCATS) [E]
 (b) (6) ; Lowy, Douglas (NCI) < (b) (6) ; Read, Sarah (NIH/NIAID) [E] (b) (6) >;
 Young, John < (b) (6) ; Adam, Stacey (FNIH) [T] (b) (6) ; Margaret Anderson
 (b) (6) ; Appell, Evan (b) (6) ; Chen, Helen Q. (b) (6) ;
 Connelly, Sarah (b) (6) ; Gonzalez, Nina (b) (6) >; Hawk, Harrison
 < (b) (6) ; Mendelson, Jesse < (b) (6) ; Menetski, Joseph (FNIH) [T]
 (b) (6) >; Nasr, Hana (b) (6) ; Santos, Michael (FNIH) [T] < (b) (6) >; Sorosa,
 Alex David (b) (6) >; Stratton, Benjamin (b) (6) >; btolman (b) (6) >;
 Tountas, Karen (FNIH) [T] (b) (6) ; Wachtel, Jonathan < (b) (6) ; Wholley, David (FNIH) [T]
 (b) (6) >
Cc: Anderson, James (NIH/OD) [E] (b) (6) >; Austin, Christopher (NIH/NCATS) [E]
 (b) (6) ; Burklow, John (NIH/OD) [E] (b) (6) >; Carluccio, Dana
 (b) (6) >; Castillejos, Carlos < (b) (6) >; FNIH Central Account
 (b) (6) >; Hallett, Adrienne (NIH/OD) [E] (b) (6) ; Lane, Cliff (NIH/NIAID) [E]
 (b) (6) >; Myles, Renate (NIH/OD) [E] < (b) (6) >; Parker, Ashley (NIH/OD) [E]
 (b) (6) ; Tabak, Lawrence (NIH/OD) [E] < (b) (6) ; Wolinetz, Carrie (NIH/OD) [E]
 < (b) (6) ; Meltzer, Abbey (FNIH) [T] (b) (6)

Subject: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, December 16, 10:00 – 11:30 a.m. Eastern U.S. Time**. The minutes from the November 19 Leadership Team call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

Join Zoom Meeting

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United Kingdom

(b) (6) United Kingdom

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Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us/> (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 6/22/2020 1:52:54 PM
To: (b) (6) (b) (6) (b) (6) Rao, Srinivas
[(b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa];
(b) (6) (b) (6) (b) (6) (b) (6)
Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera];
(b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6)
Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Diamond, Michael [(b) (6) Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Baric, Toni C [(b) (6) Rodriguez, Robin D [(b) (6) Hughes, Eric [(b) (6) Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria
 [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel,
 Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li
 [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
 Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Dave Frankowski
 [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy
 Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
 [(b) (6)]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

Subject: RE: ACTIV Preclinical full working group

Attachments: 2020-06-17_Preclinical_WG_Summary_F1.docx

Dear Preclinical Working group members and invitees,

Please review the minutes from the last full meeting of the working group. If you have any questions, or we missed anything, let me know.

Best regards,

Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

To: (b) (6) (b) (6) (b) (6) Rao, Srinivas;

(b) (6) Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins,

Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Qashu, Felicia (NIH/OD) [E];

Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette,

Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]

Cc: Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Diamond, Michael; Nancy Haigwood; Baric, Toni C;

Rodriguez, Robin D; Hughes, Eric; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Austin, Christopher

(NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin;

Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos,

Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman,

Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson,

Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Dave

Frankowski; Lowy, Douglas (NIH/NCI) [E]; Nancy Haigwood; Stratton, Benjamin; Anderson, James (NIH/OD) [E]

Subject: ACTIV Preclinical full working group

When: Wednesday, June 17, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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US (Tacoma)

US (Houston)

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Password: (b) (6)

Find your local number: <https://fnih.zoom.us/> (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 4/28/2020 1:20:15 AM

To: Eric Hughes [(b) (6)] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)] Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)] Wung, Peter /US [(b) (6)] Keith Gottesdiener [(b) (6)] Elliott Levy [(b) (6)] Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]

CC: Elizabeth Kim [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)] Salathin, Carla [(b) (6)] (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]

Subject: ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting

Attachments: ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting Agenda_04282020.pdf

Location: <https://fnih.zoom.us/> (b) (6)

Start: 4/28/2020 6:00:00 PM

End: 4/28/2020 7:00:00 PM

Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Wung, Peter /US; Keith Gottesdiener; Elliott Levy; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]

Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached our proposed agenda for tomorrow's APSG call. This agenda currently assumes that all will be able to finalize your triage of the initial list of agents by 9 am EDT tomorrow. If we do not have all of the triage reports, we will discuss a revised agenda.

Best,
Stacey

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/29/2020 7:40:20 PM
To: (b) (6) (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6)
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hughes, Eric [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutillo]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel,

Jonathan (b) (6) Prabhavathi Fernandes (b) (6) Diamond, Michael
[(b) (6) Rose Li [(b) (6) Dana Carluccio
[(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos];
Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6) Dave Frankowski [(b) (6) Baric, Toni C
[(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[(b) (6)

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Attachments: 2020-05-27_Preclinical_WG_Summary_D1.docx

This time with the attachment.

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

Please find the minutes to our meeting on Wednesday. Let me know if you have any questions or concerns with these.

Thank you,

Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

To: (b) (6) (b) (6) Menetski, Joseph (FNIH) [T]; Hild,
Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6)

(b) (6)

(b) (6)

(b) (6) ; Parker, Ashley (NIH/OD) [E]; Collins, Francis
(NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD)
[E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)

Cc: Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Gonzalez, Nina; Cutillo, Christine (NIH/NCATS) [E]; Simon, Dina (NIH/OD)
[C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine
(NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah
(NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH)
[T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael;
Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Burrus-Shaw, Cyndi
(NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint
(NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/j/1234567890> (b) (6)

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From: Stephane Bancel [(b) (6)]
Sent: 4/19/2020 7:30:29 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tal Zaks [(b) (6)]
Subject: Re: URGENT: Invitation to join the ACTIV Vaccines Working Group

Dear Francis, thank you for the invite

We have been blessed to partner with Tony and NIAID team. We look forward to it.

Tal Zaks, our CMO is leading our mRNA-1273 efforts against SARS-CoV-2 and will join that group. He is already connected to Mike Santos.

Thanks again.

See you soon

Cheers,

Stephane

From: "Collins, Francis (NIH/OD) [E]" < (b) (6) >
Date: Sunday, April 19, 2020 at 1:36 PM
To: Stephane Bancel < (b) (6) >
Cc: "Wholley, David (FNIH) [T]" < (b) (6) > "Santos, Michael (FNIH) [T]" < (b) (6) >
Subject: URGENT: Invitation to join the ACTIV Vaccines Working Group

Dear Stephane,

As you know well, addressing the COVID-19 pandemic is an urgent priority for the entire biomedical research community. While the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond, the field needs to find a way to focus and prioritize these many efforts, as there is of course still no proven treatment or vaccine.

NIH has been working at the forefront of addressing the crisis, including rapidly launching its own clinical trials of therapeutics and of course working with you at Moderna on accelerated testing of a vaccine candidate. In order to broaden the response we announced on Thursday a new public-private partnership with FDA, industry, and academic scientists to further accelerate progress against COVID and the threat of future pandemics, which we have decided to call Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV). As described in the attached meeting notes (from our kick-off on April 3) we have now set up Working Groups to decide efforts in four key areas—accelerating preclinical therapeutic development, optimizing clinical therapeutic development, coordinating clinical trials capacity, and supporting effective vaccine development.

I have heard and very much appreciate your interest in ACTIV. If you are amenable I would like to ask you if you would be willing to join as **a member on the Vaccines Working Group** which is being co-chaired by Doug Lowy of NCI and Kathrin Jansen of Pfizer. This group is charged with establishing a collaborative framework for advancing vaccine development. They are having just their second meeting tomorrow morning, so I expect there will still be plenty of areas of discussion that can benefit from your insights and expertise.

Please direct your response to this invitation to Mike Santos (b) (6) at FNIH, who will get to you immediately with the meeting logistics. I look forward to working with you on this critical effort.

Best,
Francis

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 7/16/2020 4:11:37 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
Subject: FW: ACTIV Home Nursing Playbook ready for use!

Since you asked...

From: Tountas, Karen (FNIH) [T] <(b) (6)>
Sent: Thursday, July 16, 2020 11:05 AM
To: Wholley, David (FNIH) [T] <(b) (6)>
Subject: RE: ACTIV Home Nursing Playbook ready for use!

Just an FYI... I sent this final version to the ACTIV-2 ops team and received this from Judy Currier – “Thanks Karen, This is really helpful and just in time as we work to finalize our plans for home health in ACTIV-2. It will be of great value to the ACTIV-2 team.”

Good to know all that work was not in vain! Let's hope the next four are also helpful for ACTIV. 😊

From: Tountas, Karen (FNIH) [T]
Sent: Thursday, July 16, 2020 8:58 AM
To: Colvis, Christine (NIH/NCATS) [E] <(b) (6)>; Hughes, Eric <(b) (6)>; Jansen, Kathrin <(b) (6)>; Lowy, Douglas (NCI) <(b) (6)>; Read, Sarah (NIH/NIAID) [E] <(b) (6)>; Young, John <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)>; James, Stephanie (FNIH) [T] <(b) (6)>; Menetski, Joseph (FNIH) [T] <(b) (6)>; Santos, Michael (FNIH) [T] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>; Desrosiers, Betsy <(b) (6)>; Kurilla, Michael (NIH/NCATS) [E] <(b) (6)>; Kelly, Eileen <(b) (6)>; Wachtel, Jonathan <(b) (6)>
Subject: ACTIV Home Nursing Playbook ready for use!

Dear ACTIV Working Group co-chairs,

On behalf of the ACTIV Clinical Trial Capacity Working Group, I am pleased to announce the completion of the ACTIV Home Nursing Playbook (attached). Many thanks to Betsy Desrosiers and Eileen Kelly (cc'd) and their teams at Merck and Novartis, respectively, for sharing their knowledge, lessons learned, and materials to enhance and accelerate ACTIV's clinical trial efforts. And, many thanks to Jonathan and Olivia (Deloitte) for creating an organized and user-friendly structure for these playbooks.

We know that the ACTIV-2 operations team, who has used an earlier draft of this playbook, found the details enclosed very useful and we hope that other COVID-focused clinical trial protocol and operations teams will also. Please feel free to distribute to your teams, and provide any and all feedback (positive and constructive critiques).

Of note, Betsy and Eileen have offered to make themselves and their team members available to walk through the playbook with clinical trials teams as requested.

With best regards,
Karen

Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

(b) (6) | fnihi.org

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To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Pao, William [(b) (6) Stoffels, Paul [JJCUS] [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Wolf-Rodda, Julie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89f0a08ab7224e0b9dc5a118ff336aff-wolfrodj]; Gonzalez, Nina [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time
Attachments: Agenda ACTIV EC Meeting #1 5-13-20.docx; Proposal for ACTIV leadership vF 051220.pdf

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:
Please see attached the agenda for our meeting tomorrow morning (via Zoom) and a copy of the letter from the Therapeutics- Clinical Working Group you received earlier today, for our discussion.

Please let Joe Menetski or Cheryl Melencio know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] (b) (6) ; Melencio, Cheryl (FNIH) [T] (b) (6) ; Wung, Peter /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6) Stratton, Benjamin [(b) (6)]

Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #6 (Materials Attached)

Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_23Apr2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting #6 Agenda_04222020_v2.pdf; ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 5_Key Takeaways_04222020.pdf

Location: <https://fnih.zoom.us> (b) (6)

Start: 4/23/2020 5:00:00 PM

End: 4/23/2020 6:00:00 PM

Show Time As: Busy

Required Attendees: Bozette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US; Qashu, Felicia (NIH/OD) [E]; Stratton, Benjamin

Dear TX-Clinical Master Protocol subgroup,

Please find attached the materials for today's meeting.

1. Agenda
2. Slides with some updates of what we heard decided yesterday and what we need to focus on today. We may have a few other updates a little later.
3. The high level summary of yesterday's call again for your reference.

Thanks,
Stacey

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Sent: 9/17/2020 4:27:28 PM
To: Garner, Carl [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Levy, Elliot (b) (6) Menon, Sandeep [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra (b) (6) Eisner, Mark (b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Amanda Peppercorn [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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[(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative
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DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6)
(b) (6)

CC: Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Gonzalez, Nina
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[(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
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(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon
[(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen Q.
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e];
Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk];
Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave)
CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)
(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia
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Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bcfd32930-walkerp1]; Bethany Stokes
(b) (6)]

Subject: ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200916.pdf

Location: <https://fnih.zoom.us/> (b) (6)

Start: 9/17/2020 5:00:00 PM

End: 9/17/2020 6:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Garner, Carl; Mellors, John; Levy, Elliot; Menon, Sandeep; Sizemore, Christine (NIH/FIC) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6)

Optional Attendees: Anderson, Margaret; Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes

Stacey Adam is inviting you to a scheduled Zoom meeting.

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US (San Jose)
US (San Jose)

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 6/30/2020 7:17:58 PM
To: (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell (b) (6) [(b) (6) (b) (6) Cavalieri Marco [(b) (6) (b) (6) (b) (6) (b) (6) Greg Glenn [(b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; hotez@bcm.edu; (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56f4be4598a57b423d484dcf9f-offit.email]; (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) Tal Zaks [(b) (6) (b) (6) Tolman, Brett [(b) (6) (b) (6) Hopps, Markay [(b) (6) Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; (b) (6) Jeneffer Haynes (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; (b) (6) Isabel Ramsey [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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[(b) (6) Hughes, Eric [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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(b) (6) Paul Gillard [(b) (6) Hamilton, Holli (OS/ASPR/BARDA)
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USARMY MEDCOM WRAIR (USA) [(b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som];
Schrage, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
'Wachtel, Jonathan' [(b) (6) Stratton, Benjamin [(b) (6) Anderson, Margaret
[(b) (6) (b) (6) (b) (6) Bethany Stokes
[(b) (6) Kathleen Callahan [(b) (6)

Subject: ACTIV Vaccines Working Group meeting

Location: Webex: <https://nih.webex>. (b) (6)

Start: 7/8/2020 5:15:00 PM

End: 7/8/2020 6:15:00 PM

Show Time As: Tentative

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell
(b) (6) (b) (6) Cavaleri Marco; (b) (6)
(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,
Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Seals, Jonathan
(OS/ASPR/BARDA); (b) (6) (b) (6) Tal Zaks
Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,
Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E];
Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T];
Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E];
Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul
Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil;
Schrage, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie
(CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;
(b) (6) (b) (6) Bethany Stokes; Kathleen Callahan

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From: Chen, Helen Q. [(b) (6)]
Sent: 9/9/2020 11:55:00 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

That's very helpful - thank you Ashley!

Warm regards,
Helen

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Sent: Wednesday, September 9, 2020 5:14 PM
To: Chen, Helen Q. < (b) (6) >
Cc: Adam, Stacey (FNIH) [T] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Appell, Evan < (b) (6) >
Subject: [EXT] RE: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Helen,

The hover over doesn't work in the PDF document but this will work when you display in presentation mode during the meeting tomorrow (agents in the hover over are those listed on CT.gov for each trial).

OD will work with a developer when this goes live on the ACTIV website to ensure the feature will work.

Thanks,
Ashley

-----Original Message-----

From: Chen, Helen Q. < (b) (6) >
Sent: Wednesday, September 9, 2020 4:11 PM
To: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Cc: Adam, Stacey (FNIH) [T] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Appell, Evan < (b) (6) >
Subject: FW: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Ashley,

Please see below a question from Neil. My understanding is it will be a feature once it's live on the website - is that correct? Please feel free to provide any additional information / clarification that would help address Neil's inquiry. Thank you!

Warm regards,
Helen

-----Original Message-----

From: Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6) >
Sent: Wednesday, September 9, 2020 4:07 PM
To: Chen, Helen Q. < (b) (6) >
Subject: [EXT] RE: ACTIV Therapeutics-Clinical Working Group Meeting

Thanks Helen. This has the potentially to be a really useful document. At this point, should we be able to see agent information if we hover over the black circle with an A in it? If so, that feature does not seem to be working (at least not for me).

Best,
Neil

Neil Aggarwal, MD
Chief, Lung Biology and Disease Branch
Division of Lung Diseases / NHLBI / NIH

-----Original Message-----

From: Chen, Helen Q. <(b) (6)>
Sent: Wednesday, September 9, 2020 1:27 PM
To: Adam, Stacey (FNIH) [T] <(b) (6)> Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>
Butterton, Joan <(b) (6)> De Claro, R. Angelo (FDA/CDER) <(b) (6)>
Draghia-Akli, Ruxandra <(b) (6)> Eisner, Mark <(b) (6)> Gottesdiener, Keith
<(b) (6)> Eric Hughes <(b) (6)> Judy Currier
<(b) (6)> Kim, Elizabeth <(b) (6)> LaVange, Lisa <(b) (6)>
Levy, Elliot <(b) (6)> Mellors, John W <(b) (6)> Menon, Sandeep
<(b) (6)> Parker, Ashley (NIH/OD) [E] <ashley. (b) (6)> Patel, Naimish
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(NIH/NIAID) [E] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Shen, Yuan Li
(FDA/CDER) <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> .gov>; Wholley, David
(FNIH) [T] <(b) (6)> Buchman, Tim (OS/ASPR/BARDA) (CTR) <(b) (6)> Collins, Sylva
(FDA/CDER) <(b) (6)> Amanda Peppercorn <(b) (6)> Garner, Carl
<(b) (6)> Higgs, Elizabeth (NIH/NIAID) [E] <(b) (6)> Koroshetz, Walter
(NIH/NINDS) [E] <(b) (6)> ; Timothy Burgess <(b) (6)> Reineck, Lora
(NIH/NHLBI) [E] <(b) (6)> Aggarwal, Neil (NIH/NHLBI) [E] <(b) (6)>
Rosenberg, Yves (NIH/NHLBI) [E] <(b) (6)> Goff, David (NIH/NHLBI) [E]
<(b) (6)> Brown, Jeremy (NIH/NINDS) [E] <(b) (6)> Gadbois, Ellen (NIH/OD) [E]
<(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)> >; Jacqueline Kirchner
<(b) (6)> Beigel, John (NIH) [E] <(b) (6)> Phillips, L
Revell CIV DTRA RD (USA) <(b) (6)> >; Petrovick, Martha - 0449 - MITLL
<(b) (6)> <(b) (6)> Sizemore, Christine (NIH/FIC) [E]
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Cc: Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy
<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael
(NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Young, John
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Demarcus <(b) (6)> Macone, Erin <(b) (6)> Melencio, Cheryl (FNIH) [T]
<(b) (6)> Salathin, Carla <(b) (6)> Tountas, Karen (FNIH) [T]
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Rosa Maria <(b) (6)> Gonzalez, Nina <(b) (6)> Dana Carluccio
<(b) (6)> Rose Li Central Account <(b) (6)> Margaret
Anderson <(b) (6)> Lucas Smalldon <(b) (6)> Stratton,
Benjamin <(b) (6)> <(b) (6)> Mollica, Linda /US
<(b) (6)> Oashu, Felicia (NIH/OD) [E] <(b) (6)> Patterson, Amy
(NIH/NHLBI) [E] <(b) (6)> >; Rubin, Daniel B. (FDA/CDER) <(b) (6)> .gov>; Marston,
Hilary (NIH/NIAID) [E] <(b) (6)> Wung, Peter /US <(b) (6)> Hoots, W. Keith
(NIH/NHLBI) [E] <(b) (6)> Groesch, Mary (NIH/NHLBI) [E] <(b) (6)> ; Shipp,
Allan (NIH/NHLBI) [E] <(b) (6)> Kindzelski, Andrei (NIH/NHLBI) [E]
<(b) (6)> >; Hone, David M (Dave) CIV DTRA J9 (USA) <(b) (6)> >;
Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) <(b) (6)> >; Freire, Maria (FNIH)
[T] <(b) (6)> Elsaid, Olivia <(b) (6)> Appell, Evan <(b) (6)>
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Dear ACTIV TX-Clinical Working Group Members,

As we have discussed previously, NIH has developed a table to summarize ACTIV and other NIH-supported COVID-19 trials. The goal of the table is to be informative to ACTIV and NIH leadership and to be shared more broadly once the information within it is public.

We would appreciate your review of this draft version of the table, which we are sharing ahead of tomorrow's Working Group meeting. Please do not share the table or the information in it further. We are looking forward to your input.

Warm regards,
Stacey, Mike, and Helen

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Wednesday, June 17, 2020 8:48 AM
To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; <(b) (6)>; Sizemore, Christine (NIH/FIC) [E]
Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James,

Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana
Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin;
(b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI)
[E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US;
Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski,
Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO
CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, September 10, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://secure-web.cisco.com/> (b) (6)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/23/2020 4:58:59 PM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6)]; LaVange, Lisa M [(b) (6)]; Sandeep Menon [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6)]; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; Eron, Joe [(b) (6)]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]
CC: Demarcus [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Elizabeth Kim [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [(b) (6)]; Eron, Joseph J Jr [(b) (6)]; Smith, David [(b) (6)]; Paul Klekotka [(b) (6)]; Ajay Nirula [(b) (6)]
Subject: ACTIV-2 Writing Team Meeting
Location: [https://fnih.zoom.us/j/ \(b\) \(6\)](https://fnih.zoom.us/j/ (b) (6))
Start: 5/26/2020 6:00:00 PM
End: 5/26/2020 7:00:00 PM
Show Time As: Tentative

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6) Kim, Peter (NIH/NIAID) [E]
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/30/2020 12:54:05 PM
To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #7
Location: [https://fnih.zoom.us/j/ \(b\) \(6\)](https://fnih.zoom.us/j/ (b) (6))
Start: 5/5/2020 5:00:00 PM
End: 5/5/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) [(b) (6)]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] (b) (6) [(b) (6)]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/30/2020 12:30:52 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [(b) (6) Butterson, Joan [(b) (6) Collins, Sylva (FDA/CDER) (b) (6)]; Judy Currier [(b) (6) De Claro, R. Angelo (FDA/CDER) [(b) (6) Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] (b) (6) ; Read, Sarah (NIH/NIAID) [E] [(b) (6) Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [(b) (6) Rubin, Daniel B. (FDA/CDER) [(b) (6) Shen, Yuan Li (FDA/CDER) [(b) (6) Farley, John (FDA/CDER) [(b) (6) Goff, David (NIH/NHLBI) [E] [(b) (6) Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6) Karen Lynn Price [(b) (6) Pamela Tenaerts, M.D. [(b) (6) Koroshetz, Walter (NIH/NINDS) [E] [(b) (6)]
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [ktountas@fnih.org]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] (b) (6) ; Melencio, Cheryl (FNIH) [T] (b) (6)]; Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [(b) (6) Patterson, Amy (NIH/NHLBI) [E] [(b) (6)]; Chertow, Jessica (NIH/NHLBI) [E] [(b) (6) Paltoo, Dina (NIH/NLM) [E] [(b) (6) Gibbons, Gary (NIH/NHLBI) [E] [(b) (6)]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #12
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_4May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting 4May2020 Agenda.pdf
Location: <https://fnih.zoom.us/> (b) (6)
Start: 5/4/2020 5:00:00 PM
End: 5/4/2020 6:00:00 PM
Show Time As: Busy

Required Attendees: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Koroshetz, Walter (NIH/NINDS) [E]
Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Hoots, W. Keith (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Chertow, Jessica (NIH/NHLBI) [E]; Paltoo, Dina (NIH/NLM) [E]; Gibbons, Gary (NIH/NHLBI) [E]

Dear TX-Clinical Master Protocol Subgroup,

Please find attach the materials for today's meeting.

1. Agenda
2. Slides

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/21/2020 7:05:22 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Hughes, Eric [(b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proshan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [(b) (6) Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
[(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
(b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6)
Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [dana. (b) (6) Rose
Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas
Smalldon [(b) (6) Stratton, Benjamin [(b) (6)
(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Hoots, W. Keith
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Mensah, George
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Kiley, James (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Groesch, Mary (NIH/NHLBI) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]

Subject: ACTIV TX-Clinical Working Group Meeting #8
Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200528.pdf
Location: https://fnih.zoom.us/ (b) (6)

Start: 5/28/2020 5:00:00 PM
End: 5/28/2020 6:00:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Hoots, W. Keith (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E]; Kiley, James (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]

Dear TX-Clinical WG,

Please find attached the slides for the meeting today. We will have some slight updates on the mAb criteria to discuss, but otherwise these are what we will use to review.

Thanks,

Stacey

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(b) (6) US (San Jose)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/29/2020 3:24:00 AM
To: Ab Babiker [(b) (6)] Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.cabr.um]; Thomas Murray [(b) (6)] LaVange, Lisa M [(b) (6)] Max Parmar [(b) (6)] Birgit Grund [(b) (6)] Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; David Vock [(b) (6)] Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; (b) (6) Ginny Kan [(b) (6)] (b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Paul Klekotka [(b) (6)] (b) (6) Phillips, Andrew [(b) (6)] (b) (6) Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Roger Paredes (b) (6) (b) (6) (b) (6) Shweta Sharma [(b) (6)] Moskowitz, Alan [alan. (b) (6)] Wentworth, Debby [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dc146ea82bb402cb5c6596f43056347-wentw001.um]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Joe Koopmeiners [(b) (6)] Gelijns, Annetine [(b) (6)] Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr.bios]; Andrew Phillips [(b) (6)] Jens Lundgren (b) (6) (b) (6) Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Baker, Jason [(b) (6)] (b) (6) (b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millierma2]; (b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Ginde, Adit [(b) (6)] Mark Polizzotto [(b) (6)] Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.cabr]; Proshan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Jim Neaton [(b) (6)] Sandeep Menon [(b) (6)] Karen Lynn Price [(b) (6)] (b) (6) Ajay Nirula [(b) (6)] Eric Hughes [(b) (6)] Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]
CC: Chen, Helen Q. [(b) (6)] Demarcus [(b) (6)] Bagiella, Emilia [(b) (6)] (b) (6) Wachtel, Jonathan [(b) (6)] Erhardt, William (HHS/IOS) [William. (b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Lisbeth Jørgensen [(b) (6)] Daar, Eric [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Eron, Joseph J Jr [(b) (6)] Chew, Kara M.D. [(b) (6)] Harrigan, Rachel (HHS/IOS)

[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]

Subject: ACTIV-3 Writing Team
Attachments: ACTIV_TX-Clinical_ACTIV-3 Writing Team Meeting Agenda_20200629.pdf
Location: <https://fnih.zoom.us/> (b) (6)

Start: 6/29/2020 4:00:00 PM
End: 6/29/2020 5:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Monday from 11:00 AM to 12:00 PM

Required Attendees: Ab Babiker; Neaton, Jim; Thomas Murray; Lisa LaVange; Max Parmar; Birgit Grund; Lane, Cliff (NIH/NIAID) [E]; David Vock; Rachel Harrigan; Aggarwal, Neil (NIH/NHLBI) [E]; (b) (6) Ginny Kan; (b) (6) Read, Sarah (NIH/NIAID) [E]; Paul Klekotka; (b) (6) Phillips, Andrew (b) (6) Rosenberg, Yves (NIH/NHLBI) [E]; Roger Paredes; (b) (6) Shweta Sharma; Moskowitz, Alan; Wentworth, Debby; Higgs, Elizabeth (NIH/NIAID) [E]; Joe Koopmeiners; Gelijns, Annetine; Erhardt, William (HHS/IOS); Cavan, Reilly; Andrew Phillips; Jens Lundgren; (b) (6) Kozak, Marina (OS/ASPR/BARDA); Baker, Jason; (b) (6) Judy Currier; Miller, Marissa A (NIH/NHLBI) [E]; (b) (6) Patterson, Amy (NIH/NHLBI) [E]; Ginde, Adit; Mark Polizzotto; Denning, Eileen; Proschan, Michael (NIH/NIAID) [E]; Jim Neaton; Sandeep Menon; Karen Lynn Price; (b) (6) Ajay Nirula; Eric Hughes; Reineck, Lora (NIH/NHLBI) [E]

Optional Attendees: Chen, Helen Q.; Demarcus; Bagiella, Emilia; (b) (6) (b) (6) Wachtel, Jonathan; Erhardt, William (HHS/IOS); Tountas, Karen (FNIH) [T]; Lisbeth Jørgensen; Daar, Eric; Parker, Ashley (NIH/OD) [E]; Eron, Joseph J Jr; Chew, Kara M.D.; Harrigan, Rachel (HHS/IOS)

Dear ACTIV-3 Writing Team,

Please find attached a high level agenda for tomorrow's call from 12-1pm ET.

Thanks,
Stacey

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/25/2020 2:12:38 PM
To: Young, John [(b) (6)] Pao, William [(b) (6)]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: Follow-up materials from ACTIV Leadership Team teleconference on Wednesday, April 22

Thanks, John.

William, I am also copying Joe Menetski of FNIH who supports the preclinical group that John co-chairs. We'll be sure this gets addressed. Thanks, David

From: Young, John < (b) (6) >
Sent: Saturday, April 25, 2020 3:41 AM
To: Pao, William < (b) (6) >
Cc: Freire, Maria (FNIH) [T] < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) >
Subject: Re: Follow-up materials from ACTIV Leadership Team teleconference on Wednesday, April 22

Hi William

I will take this back to the preclinical WG and we will incorporate into our plans.

Best regards

John

On Sat, 25 Apr 2020 at 9:17 AM, Pao, William < (b) (6) > wrote:

Hi David,

Nice summary.

On this comment:

Dr. William Pao noted that, given the large number of antibodies now entering clinical trials, it could be beneficial to establish a repository to share features of antibodies currently being tested (e.g., epitope and antibody format) to inform development of antibodies for future testing waves.

Please consider: the antibody features shared should be "e.g. epitope, antibody format, and other design features etc."

Also – how will my suggestion be actioned? Could the preclinical group take that on and define the features, with the mandate that all share?

Thanks!

Best,

William

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]

Sent: 24 April 2020 23:38

To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Cavaleri, Marco <(b) (6)>
Collins, Francis (NIH/OD) [E] <(b) (6)> Corey, Larry <(b) (6)> Disbrow, Gary
(OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael <(b) (6)> Erbeling, Emily
(NIH/NIAID) [E] <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Hudson, Thomas
<(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Johnson, Robert (OS/ASPR/BARDA)
<(b) (6)> Kramer, Lynn <(b) (6)> Lane, Cliff (NIH/NIAID) [E]
<(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Marston, Hilary (NIH/NIAID) [E]
<(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David
<(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Pandya, Hitesh
<(b) (6)> Pangalos, Mene <(b) (6)> Pao, William
<(b) (6)> Paul, Steve <(b) (6)> Perlmutter, Roger <(b) (6)>
Plump, Andy <(b) (6)> Rasi, Guido <(b) (6)> Reed, John
<(b) (6)> Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Skovronsky,
Daniel <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Stoffels, Paul
<(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Tsai, John
<(b) (6)> Vessey, Rupert <(b) (6)> Virgin, Skip <(b) (6)> Wholley, David
(FNIH) [T] <(b) (6)> Woodcock, Janet (FDA/CDER) <(b) (6)> Young, John
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<(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Young, John <(b) (6)>
Freire, Maria (FNIH) [T] <(b) (6)> Mammen, Mathai [JJCUS] <(b) (6)> Parker, Ashley
(NIH/OD) [E] <(b) (6)>
Cc: Barasch, Kimberly (NIH/NIAID) [C] <(b) (6)> Burrus-Shaw, Cyndi (NIH/OD) [E] <(b) (6)>
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<(b) (6)> Hoffstetter, Renata (FNIH) [T] <(b) (6)> Iberdemaj, Vaide
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[E] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Protasiewicz, Ann
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<(b) (6)> Alvarez, Rosa <(b) (6)> Anderson, Margaret <(b) (6)>
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Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)> Wholley, David (FNIH) [T]
<(b) (6)> Sepulveda, Dorina (FNIH) [T] <(b) (6)> Zottoli, Jessica
<(b) (6)> Lucas Smalldon <(b) (6)>

Subject: Follow-up materials from ACTIV Leadership Team teleconference on Wednesday, April 22

Dear ACTIV Leadership Team participants:

Thank you very much for participating in our teleconference Wednesday morning. Please find attached the summary of the meeting. Although we did not have enough time for extensive discussion on the phone, we did capture the numerous questions that were posed via the Zoom chat function and worked with the Co-chairs of our four Working Groups to answer them as well as those posed on the phone as best as possible. This is captured in the second "Q&A" document attached here. Please let us know if you feel we have not adequately answered a question--or feel free to simply reach out to me with additional questions, comments or suggestions. I will make sure they are addressed.

You should already have received calendar invitations for our next couple of update calls, which will be 90 minutes in length.

Thank you for your contributing your insights and for the participation of so many people from your organizations in ACTIV!

Regards,

David Wholley

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

fniih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 6/12/2020 3:17:38 AM

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CC: Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Chen, Helen Q. [(b) (6) Salathin, Carla [(b) (6) Lucas Smalldon [(b) (6) Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6)]

Subject: ACTIV mAb Steering Committee Meeting

Attachments: ACTIV-2-Redacted.pdf; INSIGHT014_ACTIV3_protocol_v0.4_8June2020.pdf; ACTIV_TX-Clinical_mAb Steering Committee Meeting Agenda_20200612.pdf

Location: <https://fnih.zoom.us/> (b) (6)

Start: 6/12/2020 5:00:00 PM

End: 6/12/2020 6:00:00 PM

Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin (FDA/CDER); Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER); Jens Lundgren

Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Salathin, Carla; Lucas Smalldon; Dana Carluccio; Rose Li Central Account

Dear ACTIV mAb Steering Committee,

Please find attached the agenda for tomorrow's meeting. As well as the current protocols for the ACTIV-2 and ACTIV-3 trials. They have not changed since Tuesday, but they are different from what we reviewed last week at our meeting, at least for ACTIV-3.

Thanks,
Stacey

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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6)
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose
 Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas
 Smalldon [(b) (6) Stratton, Benjamin [(b) (6)
 (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E]
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: ACTIV TX-Clinical Working Group Meeting #7

Location: <https://fnih.zoom.us/> (b) (6)

Start: 5/21/2020 6:00:00 PM

End: 5/21/2020 7:00:00 PM

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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]
Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] ((b) (6) Rubin, Daniel B.

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
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(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan];
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Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se];
(b) (6) Tal Zaks [(b) (6)
CC: Tolman, Brett [(b) (6) (b) (6) Hopps, Markay [(b) (6)
Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr];
(b) (6) (b) (6) (b) (6) (b) (6)
Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj];
(b) (6) Isabel Ramsey [(b) (6) Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
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(b) (6) Wachtel, Jonathan [(b) (6) Arvin, Ann
[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Anderson, Margaret [(b) (6) Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Bethany Stokes [(b) (6)]

Subject: ACTIV Vaccines Working Group meeting

Location: Webex: https://nih.webex. (b) (6)

Start: 5/11/2020 4:00:00 PM

End: 5/11/2020 5:00:00 PM

Show Time As: Tentative

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; (b) (6) (b) (6) (b) (6) (b) (6) Haynes, Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Offit, Paul; (b) (6) Seals, Jonathan (OS/ASPR/BARDA); (b) (6) Tal Zaks

Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]; (b) (6) (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Gonzalez, Nina; (b) (6) ; (b) (6) Wachtel, Jonathan; Arvin, Ann; Anderson, Margaret; Marston, Hilary (NIH/NIAID) [E]; Bethany Stokes

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Sent: 5/21/2020 3:02:50 PM
To: Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; LaVange, Lisa M [(b) (6)]; Eron, Joseph J Jr [(b) (6)]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6)]; Sandeep Menon [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6)]; smith.davey [(b) (6)]; chew.kara [(b) (6)]; Wohl, David A [(b) (6)]; Fischer, William A. II [(b) (6)]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; li.jonathan [(b) (6)]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: DeMarcus, Forrest [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Elizabeth Kim [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; roa.jhoanna [(b) (6)]; Smith, David [(b) (6)]; Paul Klekotka [(b) (6)]; Ajay Nirula [(b) (6)]; Elsaid, Olivia [(b) (6)]; Robert Jan Benschoep [(b) (6)]; Lei Shen [(b) (6)]
Subject: Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3
Attachments: 5401 Protocol Synopsis 051920v3.docx

Hi All:

The ACTG team was hoping to submit the A5401 protocol tomorrow to the NIAID Clinical Science Review Committee for their review. The protocol design uses standard (widely-used) statistical methods for interim and final analyses but we received the feedback (attached) from ACTIV about moving to fully use Bayesian methods, so wanted to respond and get thoughts back as this is a substantial change --- and would mean that we would not be able to send for CSRC tomorrow.

I have particular concerns about the need to use the Bayesian paradigm, particularly for Phase III. For a given agent, the Phase 3 study is a fairly simple study involving evaluations for safety, clinical symptoms, and the primary outcome measure of hospitalization/death. We proposed to use standard group sequential monitoring methods which are flexible (using the Lan-DeMets approach for flexible timing of interim analyses with an O'Brien and Fleming type stopping guideline). I think the seamless phase II to phase 3 aspect of the

design can be incorporated into this flexible approach by just considering the "look" at the data at the end of phase II as one "look" at the phase 3 primary outcome. This provides protection for the Type I error rate for each specific agent. We can overlay a the possibility of a simple futility rule, eg at $\geq 50\%$ enrollment, to allow stopping for lack of effect (can be justified using a Type II spending boundary, conditional power, or even a Bayesian type rule).

I think this is all quite straightforward. I worry that putting the Phase 3 trial into the Bayesian paradigm gains very little but adds complexity in terms of having to confirm that any Bayesian decision rule does protect Type I error rate for regulatory purposes, and in terms of explaining to many different companies and ultimately to a broad audience. In addition, if the study does go global, it increases the complexity of explaining to IRBs and other review groups.

I would prefer to leave Phase 3 using standard (widely used) statistical methods. I would also favor using standard methods for analysis of Phase 2 data but do agree that Bayesian analyses might also be used for the main efficacy outcome measures to provide an additional perspective in decision-making --- though the main graduation rules (eg observing an absolute 20% reduction in % positive for SARS-CoV-2 at an measurement time, and/or a 20% reduction in mean symptom duration) are straightforward and well-powered.

I would welcome feedback.

Many thanks,
Michael

From: Proschan, Michael (NIH/NIAID) [E] <(b) (6)>
Sent: Thursday, May 21, 2020 8:52 AM
To: LaVange, Lisa M; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey; Michael Hughes; (b) (6) chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; (b) (6) kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)
Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

I think the question is whether we could stop early for efficacy as well as stopping early for futility. That could certainly be incorporated if you think there is a realistic possibility of crossing an efficacy boundary after only 50 people. At the halfway point, the O'Brien-Fleming-like spending function boundary for the z-score is close to 3, so you would have to see a very large z-score to stop that early for efficacy.

Mike.

From: LaVange, Lisa M <(b) (6)>
Sent: Thursday, May 21, 2020 7:53 AM
To: Eron, Joseph J Jr <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Judy Currier
<(b) (6)> Eric Hughes <(b) (6)> Sandeep Menon
<(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah

(NIH/NIAID) [E] < (b) (6) Price, Dionne (FDA/CDER) < (b) (6) Rubin, Daniel B.
 (FDA/CDER) < (b) (6) Farley, John (FDA/CDER) < (b) (6) Karen Lynn Price
 < (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) Wohl, David A < (b) (6) Fischer, William A. II
 < (b) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) Roa, Jhoanna (b) (6)
 ; (b) (6) Kim, Peter (NIH/NIAID) [E] < (b) (6) Jonathan Li < (b) (6)
 Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) Kozak, Marina (OS/ASPR/BARDA)
 < (b) (6)
Cc: DeMarcus, Forrest < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan
 < (b) (6) Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)
 Jhoanna Roa < (b) (6) Smith, David < (b) (6) Paul Klekotka
 < (b) (6) Ajay Nirula < (b) (6) Elsaid, Olivia < (b) (6) Robert Jan
 Benschop < (b) (6) Lei Shen < (b) (6)
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

This seems reasonable to me. We can define any basis that we think will be important for dropping dose arms or entire agents, having little to go on at this point in terms of what best predicts hospitalizations.
 Lisa

From: Eron, Joseph J Jr

Sent: Wednesday, May 20, 2020 6:23 PM

To: Adam, Stacey (FNIH) [T] < (b) (6) Judy Currier < (b) (6) Eric Hughes
 < (b) (6) LaVange, Lisa M < (b) (6) Sandeep Menon
 < (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah
 (NIH/NIAID) [E] < (b) (6) Price, Dionne (FDA/CDER) (b) (6) Rubin, Daniel B.
 (FDA/CDER) < (b) (6) Farley, John (FDA/CDER) < (b) (6) Karen Lynn Price
 (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) Wohl, David A <david (b) (6) Fischer, William A. II
 (b) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) Roa, Jhoanna (b) (6)
 (b) (6) Kim, Peter (NIH/NIAID) [E] < (b) (6) Jonathan Li < (b) (6)
 Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) Kozak, Marina (OS/ASPR/BARDA)
 < (b) (6)
Cc: DeMarcus, Forrest (b) (6) ; Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan
 < (b) (6) Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)
 Jhoanna Roa < (b) (6) Smith, David < (b) (6) Paul Klekotka
 (b) (6) Ajay Nirula (b) (6) Elsaid, Olivia < (b) (6) Robert Jan
 Benschop (b) (6) ; Lei Shen (b) (6)
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Here is my question for the group – especially Michael, John and Lisa

My question is whether there could be an interim “activity” analysis similar to the futility analysis listed below – the reason I ask is we have very little longitudinal data on the quantitative viral shedding and it is possible that this endpoint would have substantial power such that 50 patients per arm could provide an antiviral answer.

- If the Phase 2 portion of the Clinical mAb protocol is used for dose finding, this may be challenging with respect to size of the trial (number of treatment arms needed and available sample size per treatment arm). In addition, it may be appropriate to establish an interim futility analysis based on change in quantitative viral shedding to allow for discontinuation of a dose after e.g. 50 rather than 110 patients, or to allow early discontinuation of high doses due to safety findings.

Joe Eron MD

APAR0000005318-2515123

Professor of Medicine
University of North Carolina at Chapel Hill
School of Medicine

(b) (6)

From: Adam, Stacey (FNIH) [T] < (b) (6) >

Sent: Wednesday, May 20, 2020 5:42 PM

To: Judy Currier < (b) (6) > Eric Hughes < (b) (6) > LaVange, Lisa M
<lisa. (b) (6) > Sandeep Menon < (b) (6) > Proschan, Michael (NIH/NIAID) [E]
< (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Price, Dionne (FDA/CDER)
< (b) (6) > Rubin, Daniel B. (FDA/CDER) < (b) (6) > Farley, John (FDA/CDER)
< (b) (6) > Karen Lynn Price < (b) (6) > (b) (6)
(b) (6) (b) (6) (b) (6) Wohl, David A
(b) (6) Fischer, William A. II < (b) (6) > Eron, Joseph J Jr
(b) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) > Roa, Jhoanna (b) (6)
(b) (6) Kim, Peter (NIH/NIAID) [E] < (b) (6) > Jonathan Li < (b) (6) >
Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) > Kozak, Marina (OS/ASPR/BARDA)
< (b) (6) >
Cc: DeMarcus, Forrest < (b) (6) > Tountas, Karen (FNIH) [T] < (b) (6) > Wachtel, Jonathan
< (b) (6) > Elizabeth Kim < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >
Jhoanna Roa < (b) (6) > Eron, Joseph J Jr < (b) (6) > Smith, David
< (b) (6) > Paul Klekotka < (b) (6) > Ajay Nirula < (b) (6) > Elsaid,
Olivia < (b) (6) > Robert Jan Benschop < (b) (6) > Lei Shen < (b) (6) >
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Dear mAb Outpatient WT,

The FDA team that has been working with ACTIV and sitting in on our writing team meetings for this protocol would like to offer the attached thoughts for the group's consideration on tonight's call.

Also, attaching again the updated synopsis that was discussed with the mAb Steering Committee earlier today.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

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Sent: 2/28/2021 5:57:41 PM
To: (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell (b) (6) [(b) (6) (b) (6) Cavalieri Marco [(b) (6) (b) (6) mmdavis [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user87932049]; (b) (6) Greg Glenn [(b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; (b) (6) (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fdb4e598a57b423d484dcf9f-offit.email]; (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) Tal Zaks [(b) (6) CC: Tolman, Brett [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; (b) (6) Hopps, Markay [(b) (6) Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; (b) (6) Jeneffer Haynes (b) (6) (b) (6) (b) (6) Gomez, Diana (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=06ff997304274cf78771df040baeccc7-gomezdl]; (b) (6) Isabel Ramsey [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Dieffenbach, Carl (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94acc37973d346fa98dfe16cd1bf7013-cdieffenba]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4b79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Lumsden, Joanne
 (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Desrosiers, Betsy
 [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
 (b) (6) Paul Gillard [(b) (6) François P Roman [(b) (6)
 Gonzalez Lopez, Antonio [(b) (6) Hamilton, Holli (OS/ASPR/BARDA)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; Modjarrad, Kayvon CIV
 USARMY MEDCOM WRAIR (USA) (b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange
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 Martin, Stacey (CDC/DDID/NCEZID/DVBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffe35bbdbfbfd495f97712313bedcaecc-ZMT0]; McNamara, Lucy Alexandra
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=94d2e362b03243568fa31c3d23550095-xdf4]; Goldstein, Jason
 (CDC/DDID/NCEZID/DSR) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2f414dc157843bba7369a63dfde3e5e-fex0]; Schrag, Stephanie
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Sotir, Mark
 (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b3ddfd786c14559802df76dd7b6bc49-mps6]; Thornburg, Natalie
 (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
 'Wachtel, Jonathan' (b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso];
 (b) (6) (b) (6) Bethany Stokes
 [(b) (6) Kathleen Callahan [(b) (6) Molloy, Delia (DPH)
 [(b) (6) Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Filip Dubovsky
 [(b) (6) Jacqueline Miller [(b) (6) Antonio Lanzavecchia
 [(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Harris, Rebecca /SG
 [(b) (6) Vivek Shinde [(b) (6) Cohen, Myron
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Criffield, Robin R.
 [(b) (6) Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; FNIH
 [(b) (6) Barton Haynes, M.D. [(b) (6) Michael, Nelson
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=05b9ca6b24634974b7aeb3fcaead1623-nmichael.hi]; Gilbert PhD, Peter B
 (b) (6) Bloom PhD, Jesse D (b) (6) (b) (6) ; Christopher Murray
 (b) (6) [(b) (6) Alex Sigal [(b) (6) Ho, David D.
 [(b) (6) Offit, Paul [(b) (6) Randy Hyer [(b) (6) Adam
 Bloomfield [(b) (6) Gale Smith [(b) (6) Florence, Clint (NIH/NIAID) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc];
(b) (6) (b) (6) ; Wan, Kanny (NIH/NCATS) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b478497d58dc46e4b3cfdea14f17ecd1-wankk]; (b) (6) Post,
Diane (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d283c9d5c3404cafb3119375103834a-postd]; Cassetti, Cristina (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cc6481e6535f426db66e7069ee98b644-ccassetti]; Merlin Robb
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6442891c7f7b404486500d6ed251a686-MerlinRobb]

Subject: ACTIV Vaccines Working Group meeting

Location: <https://nih.zoomgov.co> (b) (6)

Start: 3/3/2021 4:30:00 PM

End: 3/3/2021 5:30:00 PM

Show Time As: Tentative

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell
(b) (6) (b) (6) Cavaleri Marco; (b) (6)
(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,
Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Seals, Jonathan
(OS/ASPR/BARDA); (b) (6) tonya.vil (b) (6) Tal Zaks
Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
(b) (6) Gomez, Diana (NIH/NIAID) [C]; (b) (6) Isabel Ramsey; Parker,
Ashley (NIH/OD) [E]; Embry, Alan (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Dieffenbach, Carl (NIH/NIAID) [E];
Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T];
Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James,
Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Desrosiers, Betsy; Hughes,
Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; François P Roman;
Gonzalez Lopez, Antonio; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR
(USA); Kathleen Neuzil; Martin, Stacey (CDC/DDID/NCEZID/DVBD); McNamara, Lucy Alexandra
(CDC/DDID/NCIRD/DBD); Goldstein, Jason (CDC/DDID/NCEZID/DSR); Schrag, Stephanie (CDC/DDID/NCIRD/DBD);
Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Sotir, Mark (CDC/DDID/NCIRD/DVD); Thornburg, Natalie
(CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;
(b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Molloy,
Delia (DPH); Wood, Gretchen (NIH/OD) [E]; Filip Dubovsky; Jacqueline Miller; Antonio Lanzavecchia; Ann Arvin;
Harris, Rebecca /SG; Vivek Shinde; Cohen, Myron; Criffield, Robin R.; Marovich, Mary (NIH/NIAID) [E]; FNIH; Barton
Haynes, M.D.; Nelson Michael; Gilbert PhD, Peter B; Bloom PhD, Jesse D; (b) (6) ; Christopher Murray;
pennym; Alex Sigal; Ho, David D.; Offit, Paul; Randy Hyer; Adam Bloomfield; Gale Smith; Florence, Clint (NIH/NIAID)
[E]; (b) (6) (b) (6) Wan, Kanny (NIH/NCATS) [C];
(b) (6) Post, Diane (NIH/NIAID) [E]; Cassetti, Cristina (NIH/NIAID) [E]; Merlin Robb

<https://nih.zoomgov.> (b) (6)

Meeting ID: (b) (6)

Passcode: (b) (6)

One tap mobile

(b) (6) US (San Jose)
US (New York)

Dial by your location

(b) (6)

US (San Jose)
US (New York)
US
US (San Jose)

Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://nih.zoomgov.com/> (b) (6)

Join by SIP

(b) (6)

Join by H.323

(b) (6) (US West)
(b) (6) (US East)

Meeting ID: (b) (6)

Passcode: (b) (6)

From: Prabha Fernandes [(b) (6)]
Sent: 5/29/2020 7:31:05 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; 'Rao, Srinivas' (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; 'Tomas Cihlar' [(b) (6) 'Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)' [(b) (6)
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; 'Hughes, Eric' [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Cutillo, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c04c8f5063c34361bb7491f216f75adc-cutilloc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; 'Desrosiers, Betsy' [(b) (6) 'Jansen, Kathrin' (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; 'Alvarez, Rosa Maria' [(b) (6) 'Kim, Elizabeth' [(b) (6) 'Tolman, Brett' [(b) (6)

'Wachtel, Jonathan' [(b) (6)] 'Prabhavathi Fernandes' [prabha. (b) (6)] 'Diamond, Michael' [(b) (6)] 'Rose Li' (b) (6) 'Dana Carluccio' [(b) (6)]
Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos];
Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; 'Rodriguez, Robin D' [(b) (6)] 'Dave Frankowski' [(b) (6)] 'Baric, Toni C' [(b) (6)]
Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; 'Stratton, Benjamin' [(b) (6)]

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Attachments: GC376 A vet feline infectious peritonitis Anivive .pdf; GC376 JJ Virology 2015-Kim-feline coronavirusl - Copy.pdf

Hi Joe,

When we prioritize re-purposed drugs..

Should we should include vet products. Anvive has announced it data on SARS CoV2.. they have been developing the compound for feline infectious peritonitis. Protease inhibitor.

Oral product.

Selectivity index is great..

Attached FYI in case you have not seen.

Regards,

Prabha

From: Menetski, Joseph (FNIH) [T] < (b) (6) >

Sent: Friday, May 29, 2020 3:25 PM

To: (b) (6) (b) (6) david.j. (b) (6) Hild, Sheri (NIH/OD) [E]

< (b) (6) (b) (6) (b) (6) >

(b) (6) (b) (6) Baric, Ralph < (b) (6) (b) (6) Ottinger,

Elizabeth (NIH/NCATS) [E] < (b) (6) Colvis, Christine (NIH/NCATS) [E] < (b) (6)

Hewitt, Judith (NIH/NIAID) [E] < (b) (6) Deming, Damon (FDA/CDER) < (b) (6)

(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]

< (b) (6) (b) (6) Adams, Peter (OS/ASPR/BARDA)

< (b) (6) Rao, Srinivas < (b) (6) Qashu, Felicia (NIH/OD) [E]

< (b) (6) Tomas Cihlar < (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID

(USA) < (b) (6) >

Cc: Gadbois, Ellen (NIH/OD) [E] < (b) (6) Hughes, Eric < (b) (6) Gonzalez, Nina

< (b) (6) Cutillo, Christine (NIH/NCATS) [E] < (b) (6) Simon, Dina (NIH/OD) [C]

< (b) (6) Wholley, David (FNIH) [T] < (b) (6) Austin, Christopher (NIH/NCATS) [E]

< (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Colvis, Christine (NIH/NCATS) [E]

< (b) (6) Desrosiers, Betsy < (b) (6) Jansen, Kathrin

< (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI)

< (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6)

Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) James, Stephanie (FNIH)

[T] < (b) (6) Alvarez, Rosa Maria < (b) (6) Kim, Elizabeth < (b) (6) Tolman,

Brett < (b) (6) > Wachtel, Jonathan < (b) (6) > Prabhavathi Fernandes
< (b) (6) > Diamond, Michael < (b) (6) > Rose Li
< (b) (6) > Dana Carluccio < (b) (6) > Lagos, Enrique (NIH/NCATS) [E]
< (b) (6) > Jonson, Samantha (NIH/NCATS) [E] < (b) (6) > Burrus-Shaw, Cyndi
(NIH/OD) [E] < (b) (6) > Rodriguez, Robin D < (b) (6) > Dave Frankowski
< (b) (6) > Baric, Toni C < (b) (6) > Lowy, Douglas (NIH/NCI) [E]
< (b) (6) > Florence, Clint (NIH/NIAID) [E] < (b) (6) > Nancy Haigwood
< (b) (6) > Stratton, Benjamin < (b) (6) >

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Dear Preclinical group and attendees,

Please find the minutes to our meeting on Wednesday. Let me know if you have any questions or concerns with these.

Thank you,

Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

To: (b) (6); Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6)

(b) (6)

(b) (6)

(b) (6)

; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) (Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)

Cc: Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Gonzalez, Nina; Cutillo, Christine (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Wednesday, May 27, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: [https://fnih.zoom.us/j/\(b\) \(6\)](https://fnih.zoom.us/j/(b) (6))

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

[https://fnih.zoom.us/j/\(b\) \(6\)](https://fnih.zoom.us/j/(b) (6))

Meeting ID: (b) (6)

Password: (b) (6)

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(b) (6)

US (Germantown)

US (Chicago)

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US (Germantown)

US (Chicago)

US (New York)

US (San Jose)

US (San Jose)

US (Tacoma)

US (Houston)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 6/15/2020 7:48:50 PM
To: Vincent, Mike [(b) (6)]; Bascles, Lionel [(b) (6)]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6)]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos [(b) (6)]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Kublin MD, MPH, James [(b) (6)]; Ferguson, Sue [(b) (6)]
CC: Takas, Therese [(b) (6)]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hughes, Eric [(b) (6)]; Wachtel, Jonathan [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin [(b) (6)]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana [(b) (6)]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6)]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6)]; Hamilton, Nancy [(b) (6)]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Minnich, Beth
(b) (6); Mueller-Reichenstein, Petra (b) (6) Pico, Dianna
(NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora
(b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Culp, Michelle (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Kenny, Dermot
(b) (6) (b) (6)

Subject: Canceled: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Location: <https://fnih.zoom.us/j> (b) (6)

Start: 6/16/2020 1:00:00 PM

End: 6/16/2020 2:00:00 PM

Show Time As: Free

Recurrence: Weekly

every Tuesday from 9:00 AM to 10:00 AM

Required Attendees: Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzone; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Weinmann, Gail; Kublin MD, MPH, James; Ferguson, Sue
Optional Attendees: Takas, Therese; Gadbois, Ellen (NIH/OD) [E]; Hughes, Eric; Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E] (b) (6) Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6) Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Hill, Zoe (NIH/NHLBI) [C]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] (b) (6); Culp, Michelle (NIH/OD) [E]; Kenny, Dermot;
(b) (6)

Dear Clinical Trial Capacity Working Group Members – This **call will be canceled for 16 June 2020**. You get 1 hour back to your week – Enjoy! The **next call for the working group is scheduled for 23 June 2020** at 9 am eastern US time. Best regards, Karen

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our ACTIV mandate – looking forward to operationalizing the outcomes of your efforts. Let's continue to meet regularly through the month of June (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=Exchange ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/24/2020 12:30:30 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4fae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Stratton, Benjamin [(b) (6)
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_24Apr2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting #7 Agenda_04222020.pdf; Drug-info-COVID-19-Visante-4-21.pdf
Location: https://fnih.zoom.us/j/ (b) (6)
Start: 4/24/2020 2:00:00 PM
End: 4/24/2020 3:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US; Qashu, Felicia (NIH/OD) [E]; Stratton, Benjamin

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for tomorrow's meeting.

1. Agenda
2. Slides for discussion updated with the decisions from today
3. A useful resource about current standard clinical treatment guidelines from the front lines for COVID. This may be a useful resource in selecting how to do minimal data collection and trying to understand SOC.

Please let me know if you have questions or other things you think would be helpful for the group to review.

Thanks,
Stacey

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From: Michael Hughes [(b) (6)]
Sent: 5/21/2020 5:54:02 PM
To: LaVange, Lisa M [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Eron, Joseph J Jr [(b) (6)]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6)]; Sandeep Menon [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6)]; smith.davey [(b) (6)]; chew.kara [(b) (6)]; Wohl, David A [(b) (6)]; Fischer, William A. II [(b) (6)]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; li.jonathan [(b) (6)]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]
CC: DeMarcus, Forrest [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Elizabeth Kim [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; roa.jhoanna [(b) (6)]; Smith, David [(b) (6)]; Paul Klekotka [(b) (6)]; Ajay Nirula [(b) (6)]; Elsaid, Olivia [(b) (6)]; Robert Jan Benschoep [(b) (6)]; Lei Shen [(b) (6)]
Subject: Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Hi Lisa,

That's fine. Perhaps you and Karen could circulate some brief details of the Bayesian model framework and associated priors for each outcome measure you are envisaging? --- I think that would help in moving things along.

Looking forward to discussing,

Michael

From: LaVange, Lisa M < (b) (6) >
Sent: Thursday, May 21, 2020 1:34 PM

APAR0000005312-2515130

To: Michael Hughes; Proschan, Michael (NIH/NIAID) [E]; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey; (b) (6) chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; (b) (6) kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)

Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaïd, Olivia; Robert Jan Benschop; Lei Shen

Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks, Michael. I believe it is premature to submit the protocol to your internal review committee. My take-away from yesterday's meeting was that the next step would be for the subgroup of statisticians to meet to discuss the simulations required for the revised trial design. The proposed revisions to the design are needed, in my opinion, to give us the type of flexible, fast-moving master protocol we need to screen a large amount of monoclonal antibodies. But we need to work out some of the design details, so let's have that next meeting as planned. Hoping we can schedule it for some time tomorrow and will work with Stacey to find a time.

Lisa

From: Michael Hughes [mailto:(b) (6)]

Sent: Thursday, May 21, 2020 11:03 AM

To: Proschan, Michael (NIH/NIAID) [E] <(b) (6)> LaVange, Lisa M <(b) (6)> Eron, Joseph J Jr <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> currier.judith <(b) (6)> Eric Hughes <(b) (6)> Sandeep Menon <(b) (6)> read.sarah <(b) (6)> Price, Dionne (FDA/CDER) <(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)> Farley, John (FDA/CDER) <(b) (6)> Karen Lynn Price <(b) (6)> smith.davey <(b) (6)> chew.kara <(b) (6)> Wohl, David A <(b) (6)> Fischer, William A. II <(b) (6)> javan.arzhang <(b) (6)> Roa, Jhoanna <(b) (6)> kim.peter <(b) (6)> li.jonathan <(b) (6)> Marks, Gilbert (OS/ASPR/BARDA) (CTR) <(b) (6)> Kozak, Marina (OS/ASPR/BARDA) <(b) (6)>

Cc: DeMarcus, Forrest <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)> Elizabeth Kim <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> roa.jhoanna <(b) (6)> Smith, David <(b) (6)> Paul Klekotka <(b) (6)> Ajay Nirula <(b) (6)> Elsaïd, Olivia <(b) (6)> Robert Jan Benschop <(b) (6)> Lei Shen <(b) (6)>

Subject: Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Hi All:

The ACTG team was hoping to submit the A5401 protocol tomorrow to the NIAID Clinical Science Review Committee for their review. The protocol design uses standard (widely-used) statistical methods for interim and final analyses but we received the feedback (attached) from ACTIV about moving to fully use Bayesian methods, so wanted to respond and get thoughts back as this is a substantial change --- and would mean that we would not be able to send for CSRC tomorrow.

I have particular concerns about the need to use the Bayesian paradigm, particularly for Phase III. For a given agent, the Phase 3 study is a fairly simple study involving evaluations for safety, clinical symptoms, and the primary outcome measure of hospitalization/death. We proposed to use standard group sequential monitoring methods which are flexible (using the Lan-DeMets approach for flexible timing of interim analyses with an O'Brien and Fleming type stopping guideline). I think the seamless phase II to phase 3 aspect of the design can be incorporated into this flexible approach by just considering the "look" at the data at the end of

phase II as one "look" at the phase 3 primary outcome. This provides protection for the Type I error rate for each specific agent. We can overlay a the possibility of a simple futility rule, eg at $\geq 50\%$ enrollment, to allow stopping for lack of effect (can be justified using a Type II spending boundary, conditional power, or even a Bayesian type rule).

I think this is all quite straightforward. I worry that putting the Phase 3 trial into the Bayesian paradigm gains very little but adds complexity in terms of having to confirm that any Bayesian decision rule does protect Type I error rate for regulatory purposes, and in terms of explaining to many different companies and ultimately to a broad audience. In addition, if the study does go global, it increases the complexity of explaining to IRBs and other review groups.

I would prefer to leave Phase 3 using standard (widely used) statistical methods. I would also favor using standard methods for analysis of Phase 2 data but do agree that Bayesian analyses might also be used for the main efficacy outcome measures to provide an additional perspective in decision-making --- though the main graduation rules (eg observing an absolute 20% reduction in % positive for SARS-CoV-2 at an measurement time, and/or a 20% reduction in mean symptom duration) are straightforward and well-powered.

I would welcome feedback.

Many thanks,
Michael

From: Proschan, Michael (NIH/NIAID) [E] <(b) (6)>
Sent: Thursday, May 21, 2020 8:52 AM
To: LaVange, Lisa M; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey; Michael Hughes; (b) (6) chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; (b) (6) kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)
Cc: DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

I think the question is whether we could stop early for efficacy as well as stopping early for futility. That could certainly be incorporated if you think there is a realistic possibility of crossing an efficacy boundary after only 50 people. At the halfway point, the O'Brien-Fleming-like spending function boundary for the z-score is close to 3, so you would have to see a very large z-score to stop that early for efficacy.

Mike.

From: LaVange, Lisa M <(b) (6)>
Sent: Thursday, May 21, 2020 7:53 AM
To: Eron, Joseph J Jr <joseph (b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Judy Currier
<(b) (6)> Eric Hughes <(b) (6)> Sandeep Menon
<(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah
(NIH/NIAID) [E] <(b) (6)> Price, Dionne (FDA/CDER) <(b) (6)> Rubin, Daniel B.
(FDA/CDER) <(b) (6)> Farley, John (FDA/CDER) <(b) (6)> Karen Lynn Price

(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Wohl, David A (b) (6) Fischer, William A. II
(b) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) Roa, Jhoanna (b) (6)
(b) (6) Kim, Peter (NIH/NIAID) [E] < (b) (6) Jonathan Li < (b) (6)
Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) Kozak, Marina (OS/ASPR/BARDA)
< (b) (6)
Cc: DeMarcus, Forrest < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan
< (b) (6) Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)
Jhoanna Roa < (b) (6) Smith, David < (b) (6) Paul Klekotka
(b) (6) Ajay Nirula (b) (6) Elsaid, Olivia < (b) (6) Robert Jan
Benschop (b) (6) Lei Shen (b) (6)
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

This seems reasonable to me. We can define any basis that we think will be important for dropping dose arms or entire agents, having little to go on at this point in terms of what best predicts hospitalizations.
Lisa

From: Eron, Joseph J Jr
Sent: Wednesday, May 20, 2020 6:23 PM
To: Adam, Stacey (FNIH) [T] < (b) (6) Judy Currier < (b) (6) Eric Hughes
< (b) (6) LaVange, Lisa M < (b) (6) Sandeep Menon
< (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah
(NIH/NIAID) [E] < (b) (6) Price, Dionne (FDA/CDER) < (b) (6) Rubin, Daniel B.
(FDA/CDER) < (b) (6) Farley, John (FDA/CDER) < (b) (6) Karen Lynn Price
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Wohl, David A (b) (6) Fischer, William A. II
(b) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) Roa, Jhoanna (b) (6)
; (b) (6) Kim, Peter (NIH/NIAID) [E] < (b) (6) Jonathan Li < (b) (6)
Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) Kozak, Marina (OS/ASPR/BARDA)
< (b) (6)
Cc: DeMarcus, Forrest < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan
< (b) (6) Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)
Jhoanna Roa < (b) (6) Smith, David < (b) (6) Paul Klekotka
(b) (6) Ajay Nirula (b) (6) Elsaid, Olivia < (b) (6) Robert Jan
Benschop (b) (6) Lei Shen (b) (6)
Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Here is my question for the group – especially Michael, John and Lisa
My question is whether there could be an interim “activity” analysis similar to the futility analysis listed below – the reason I ask is we have very little longitudinal data on the quantitative viral shedding and it is possible that this endpoint would have substantial power such that 50 patients per arm could provide an antiviral answer.

- If the Phase 2 portion of the Clinical mAb protocol is used for dose finding, this may be challenging with respect to size of the trial (number of treatment arms needed and available sample size per treatment arm). In addition, it may be appropriate to establish an interim futility analysis based on change in quantitative viral shedding to allow for discontinuation of a dose after e.g. 50 rather than 110 patients, or to allow early discontinuation of high doses due to safety findings.

Joe Eron MD
Professor of Medicine
University of North Carolina at Chapel Hill
School of Medicine

(b) (6)

From: Adam, Stacey (FNIH) [T] < (b) (6) >

Sent: Wednesday, May 20, 2020 5:42 PM

To: Judy Currier < (b) (6) > Eric Hughes < (b) (6) > LaVange, Lisa M
< (b) (6) > Sandeep Menon < (b) (6) > Proschan, Michael (NIH/NIAID) [E]
< (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Price, Dionne (FDA/CDER)
< (b) (6) > Rubin, Daniel B. (FDA/CDER) < (b) (6) > Farley, John (FDA/CDER)
< (b) (6) > Karen Lynn Price <price_karen (b) (6) > (b) (6)
(b) (6) (b) (6) (b) (6) Wohl, David A
(b) (6) Fischer, William A. II (b) (6) Eron, Joseph J Jr
(b) (6) Javan, Arzhang (NIH/NIAID) [E] < (b) (6) > Roa, Jhoanna (b) (6)
(b) (6) Kim, Peter (NIH/NIAID) [E] < (b) (6) > Jonathan Li < (b) (6) >
Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) > Kozak, Marina (OS/ASPR/BARDA)
< (b) (6) >

Cc: DeMarcus, Forrest < (b) (6) > Tountas, Karen (FNIH) [T] < (b) (6) > Wachtel, Jonathan
< (b) (6) > Elizabeth Kim < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >
Jhoanna Roa < (b) (6) > Eron, Joseph J Jr (b) (6) Smith, David
< (b) (6) > Paul Klekotka (b) (6) Ajay Nirula (b) (6) Elsaid,
Olivia < (b) (6) > Robert Jan Benschop (b) (6) Lei Shen (b) (6)

Subject: RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Dear mAb Outpatient WT,

The FDA team that has been working with ACTIV and sitting in on our writing team meetings for this protocol would like to offer the attached thoughts for the group's consideration on tonight's call.

Also, attaching again the updated synopsis that was discussed with the mAb Steering Committee earlier today.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

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US (San Jose)

US (San Jose)

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/11/2020 2:08:35 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Pao, William [(b) (6) Stoffels, Paul [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Protasiewicz, Ann [(b) (6) Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Zanelato, Ann
[(b) (6) Zottoli, Jessica [(b) (6) Togashi, Mieko (NIH/NCI) [E]
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Lagos, Enrique
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Hardesty, Rebecca (NIH/OD)
[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]; Alvarez, Rosa
[(b) (6)]; Anderson, Margaret [(b) (6) Elsaid, Olivia
[(b) (6) Gonzalez, Nina [(b) (6) Kim, Elizabeth [(b) (6)]; Stratton,
Ben [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6)

Subject: ACTIV mtg with Exec Comm and WG co-chairs

Attachments: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time; Notes _Agenda ACTIV EC Meeting #1
5-13-20.docx

Location: <https://fnih.zoom.us/> (b) (6)

Start: 5/13/2020 12:00:00 PM

End: 5/13/2020 1:00:00 PM

Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Freire, Maria (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Wolinetz, Carrie (NIH/OD) [E]
Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Zanelato, Ann; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Hardesty, Rebecca (NIH/OD) [C]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan

Cheryl Melencio is inviting you to a scheduled Zoom meeting.

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 2/17/2021 1:06:04 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, February 17, 2021
Attachments: 02.17.21 ACTIV EC and Leadership Team Meeting 20210216_vF.pdf; 02.17.21 ACTIV EC and Leadership Team Meeting_APPENDIX_20210216_vF.pdf; 2021-01-14_ACTIV_Leadership_Team_and_Executive_Committee_Meeting_Summary_vF.pdf

FYI

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, February 16, 2021 7:03 PM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane
<(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco
<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]
<(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
Victoria Davey <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael
<(b) (6)> Embry, Alan (NIH/NIAID) [E] <(b) (6)> Erbeling, Emily (NIH/NIAID) [E]
<(b) (6)> Erck, Stan <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>
Freire, Maria (FNIH) [T] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Gibbons, Gary
(NIH/NHLBI) [E] <(b) (6)> Hudson, Thomas <(b) (6)> James, Stephanie (FNIH) [T]
<(b) (6)> Johnson, Robert (OS/ASPR/BARDA) <(b) (6)> Kramer, Lynn
<(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Lepore, John <(b) (6)>
Marks, Peter (FDA/CBER) <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker,
David <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Messonnier, Nancy
(CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh <(b) (6)> Pangalos, Mene
<(b) (6)> Pao, William <(b) (6)> Parker, Ashley (NIH/OD) [E]
<(b) (6)> Paul, Steve <(b) (6)> Perlmutter, Roger <(b) (6)>
Plenge, Robert <(b) (6)> Plump, Andy <(b) (6)> Rachel Ramoni
<(b) (6)> Reed, John <(b) (6)> Reese, David <(b) (6)> Rouse, Doris
<(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Skovronsky, Daniel <(b) (6)>
Stein, Peter (FDA/CDER) <(b) (6)> Stoffels, Paul <(b) (6)> Tabak, Lawrence (NIH/OD)
[E] <(b) (6)> Talley, Michael <(b) (6)> Tsai, John <(b) (6)>
Vessey, Rupert <(b) (6)> Virgin, Skip <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>
Woodcock, Janet (FDA/OC) <(b) (6)> Young, John <(b) (6)> Colvis,
Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy <(b) (6)> Eric
Hughes <(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]
<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>
Young, John <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)> .gov>;
Carluccio, Dana <(b) (6)> Castillejos, Carlos <(b) (6)> Culp, Michelle
(NIH/OD) [E] <(b) (6)> FNIH Central Account <(b) (6)> Gadbois, Ellen (NIH/OD) [E]
<(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Lumsden, Joanne (NIH/NCATS) [C]
<(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E]
<(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Margaret Anderson
<(b) (6)> Appell, Evan <(b) (6)> Chen, Helen <(b) (6)>
Connelly, Sarah <(b) (6)> Dally, Nicole <(b) (6)> Gonzalez, Nina
<(b) (6)> Hawk, Harrison <(b) (6)> Mendelson, Jesse <(b) (6)>
Menetski, Joseph (FNIH) [T] <(b) (6)> Nasr, Hana <(b) (6)> Santos, Michael (FNIH) [T]
<(b) (6)> Sorosa, Alex <(b) (6)> Stratton, Benjamin <(b) (6)> Tolman,

Brett < (b) (6) > Wachtel, Jonathan < (b) (6) > Wholley, David (FNIH) [T]
< (b) (6) > Burklow, John (NIH/OD) [E] < (b) (6) > Hallett, Adrienne (NIH/OD) [E]
< (b) (6) > Meltzer, Abbey (FNIH) [T] < (b) (6) > Myles, Renate (NIH/OD) [E]
< (b) (6) > Wolinetz, Carrie (NIH/OD) [E] < (b) (6) >

Subject: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, February 17, 2021

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, February 17, from 11:30 a.m. to 1:00 p.m. Eastern U.S. Time.** The minutes from the January 14 Executive Committee/Leadership Team call are also attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/26/2020 1:23:01 AM
To: Jim Neaton [(b) (6)]; Jens Lundgren [(b) (6)]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Karen Lynn Price [(b) (6)]; LaVange, Lisa M [(b) (6)]; Sandeep Menon [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; [(b) (6)]; Gelijns, Annetine [(b) (6)]; Moskowitz, Alan [(b) (6)]; Ab Babiker [(b) (6)]; Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr.bios]; Phillips, Andrew [(b) (6)]; Birgit Grund [(b) (6)]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.ccbcr.um]; Joe Koopmeiners [(b) (6)]; David Vock [(b) (6)]; Thomas Murray [(b) (6)]; Max Parmar [(b) (6)]; Mark Polizzotto [(b) (6)]; Ginny Kan [(b) (6)]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Baker, Jason [(b) (6)]; Roger Paredes [(b) (6)]; [(b) (6)]; [(b) (6)]; M [(b) (6)]; [(b) (6)]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; [(b) (6)]; [(b) (6)]; Ajay Nirula [(b) (6)]; Paul Klekotka [(b) (6)]; Ginde, Adit [(b) (6)]; Andrew Phillips [(b) (6)]; [(b) (6)]; Wentworth, Debby [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dc146ea82bb402cb5c6596f43056347-wentw001.um]; Shweta Sharma [(b) (6)]; [(b) (6)]; Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.ccbcr];
CC: Demarcus [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [(b) (6)]; Eron, Joseph J Jr [(b) (6)]; Chew, Kara M.D. [(b) (6)]; Daar, Eric [(b) (6)]; Bagiella, Emilia [(b) (6)]; [(b) (6)]; Lisbeth Jørgensen [lisbeth. [(b) (6)]]; Erhardt, William (HHS/IOS) [(b) (6)]; [(b) (6)]; [(b) (6)]

Subject: ACTIV-3 Writing Team

Location: [\(b\) \(6\)](https://fnih.zoom.us/j/ (b) (6))

Start: 6/29/2020 3:00:00 PM

End: 6/29/2020 4:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Monday from 11:00 AM to 12:00 PM

Required Attendees: Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Reineck, Lora (NIH/NHLBI) [E]; Judy Currier; Karen Lynn Price; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; Erhardt, William (OS/ASA/OCIO/DCIO-Ops) (CTR);

(b) (6) Gelijns, Annetine; Moskowitz, Alan; Ab Babiker; Cavan, Reilly; Phillips, Andrew
(b) (6) Birgit Grund; Neaton, Jim; Joe Koopmeiners; David Vock; Thomas Murray; Max Parmar;

Mark Polizzotto; Ginny Kan; Lane, Cliff (NIH/NIAID) [E]; Baker, Jason; Roger Paredes; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6) Rosenberg, Yves
(NIH/NHLBI) [E]; (b) (6) (b) (6) Ajay Nirula; Paul Klekotka; Ginde, Adit;
Andrew Phillips; (b) (6) Wentworth, Debby; Shweta Sharma; (b) (6) Denning,
Eileen

Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Eron, Joseph J Jr; Chew, Kara M.D.; Daar, Eric; Bagiella, Emilia; (b) (6) Lisbeth Jørgensen;
Erhardt, William (HHS/IOS); (b) (6)

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 4/29/2020 10:33:44 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6)
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(b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li [(b) (6) Dana Carluccio (b) (6) ; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy); Rodriguez, Robin D

[(b) (6) Dave Frankowski [david. (b) (6)

Subject: RE: ACTIV Preclinical working group (Friday meeting)

Hi all,

Please find below our agenda for tomorrow's WG meeting. We have a few topics that we want to discuss and get feedback from the entire WG before going our presentation to the ACTIV leadership next week. Please note that we are extending our meeting until 12:30pm.

Agenda Topic	Duration	Facilitator
Provide overview of agenda topics	5 mins	Christine Colvis, John Young
Discuss prioritization filter scheme for antiviral molecules	25 mins	Kara Carter, Jay Grobler
Discuss NHP Strategy Framework	25 mins	Jay Rappaport
Discuss pending cross-subgroup questions/decisions E.g. Better understand the use of adaptive viruses in small animal model studies	20 mins	Cat Lutz, Mike Diamond
Align on next steps	10 mins	Joe Menetski, Rosa Alvarez

Sincerely,

Joseph Menetski

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] < (b) (6)

Sent: Tuesday, April 14, 2020 6:49 PM

To: Menetski, Joseph (FNIH) [T]; (b) (6) (b) (6) (b) (6)

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(b) (6) Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6)

(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];

(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US

Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski

APAR0000004905-2515134

Subject: ACTIV Preclinical working group (Friday meeting)

When: Thursday, April 30, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

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Joseph P. Menetski Ph.D.

Associate Vice President, Research Partnerships

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Sent: 6/16/2020 5:42:43 PM
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CC: Demarcus [(b) (6)] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera]; Chen, Helen Q. [(b) (6)] Eron, Joseph J Jr [(b) (6)] Chew, Kara M.D. [(b) (6)] Daar, Eric [(b) (6)] Bagiella, Emilia [(b) (6)]
Subject: Follow-up from ACTIV-3 Writing Team Meeting 06/15/2020
Attachments: ACTIV_Therapeutics-Clinical_Master Protocol Subgroup_ACTIV-3 Writing Team Meeting Minutes_20200615.pdf; ACTIV3_INSIGHT014_16June2020.pdf

Dear ACTIV-3 Writing Team,

Please find the summary notes from yesterday's discussion. In addition, please find attached a slightly updated version of the slides that Jens presented for reference.

APAR0000005173-2515135

As an immediate follow-up on the CDA, NIAID is working on executing a new CDA with Lilly to allow this team to have access to the necessary data for the Appendix H writing.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
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CC: Tolman, Brett [(b) (6) Jessica. (b) (6) Hopps, Markay [(b) (6) Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; (b) (6) Jeneffer Haynes (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; (b) (6) Isabel Ramsey [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John

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To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Hughes, Eric [(b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish (b) (6); Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proshan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose

Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas
Smalldon [(b) (6) Stratton, Benjamin [(b) (6) Mollica, Linda
/US [Linda. (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: ACTIV Therapeutics-Clinical Working Group - Meeting #3 (Materials Attached)

Attachments: ACTIV Therapeutics-Clinical WG 23Apr2020 Meeting Guide 04222020.pdf; ACTIV Therapeutics-Clinical WG
23Apr2020 Agenda 04222020_v2.pdf; ACTIVPrioritizationCriteria-v3.xlsx; 2020-04-
20_Clinical_Trial_Capacity_Inventory_Sub-WG_Summary_FINAL.pdf; 2020-04-
19_Clinical_Trial_Capacity_Inventory_Sub-WG_Summary-FINAL.pdf;
Clinical_Trial_Capacity_Working_Group_Meeting #2_Summary_FINAL.pdf;
Clinical_Trial_Capacity_WG_meeting#1_Summary.pdf

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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner,
Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John;
Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael;
Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH)
[T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs,
Elizabeth (NIH/NIAID) [E]

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas
(NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;
Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman,
Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon;
Stratton, Benjamin; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]

Dear COVID PPP Therapeutics-Clinical WG Members and Co-Chairs from other WGs,

Please find attached the materials for today's meeting.

1. Agenda
2. Slides – Summarizing progress by both groups for discussion
3. Updated Prioritization Criteria (Excel Spreadsheet)
4. Summaries from the CTC WG (4 of them) – This is to keep us aware of what our sister WG is doing. At future meetings we will be having them provide a quick update on progress and what they need from us.

As always please let me know if you have any questions before the meeting, if not see you all at 2pm!

Thanks,
Stacey

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on behalf of Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
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Subject: Materials for June 3 ACTIV Partnership Leadership Call
Attachments: Zoom instructions for June 3 2020 call final_.docx; 2020-05-06_ACTIV_Leadership_Group_Meeting_Summary FINAL.pdf; ACTIV Leadership Team Meeting 20200603 FINAL.pptx

Dear Colleagues:

Thank you very much for taking time to join Francis Collins, Paul Stoffels, and the rest of our Executive Committee tomorrow, June 3, from 12:00 p.m. – 1:30 p.m. Eastern U.S. time to discuss the considerable progress of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership since our last call on May 6. You should have received a calendar invitation for the teleconference, which FNIH will be hosting. Please contact Cheryl Melencio and Joe Menetski at FNIH if you have any issues preparing for or signing into Zoom for the teleconference (b) (6) or (b) (6).

Attached you will find the following materials for the meeting:

- 1) The PowerPoint slide deck for the meeting, which includes the meeting agenda
- 2) The meeting minutes from our May 6 meeting (previously sent to you on May 8)
- 3) Instructions on how to use the Zoom app to access and participate in the meeting.

We look forward to speaking with you tomorrow and hearing your feedback.

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Regards,

David Wholley

APAR0000020288-2515138

Senior Vice President, Research Partnerships
Foundation for the National Institutes of Health

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/11/2020 6:59:57 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Jim Neaton [(b) (6) Jens Lundgren [(b) (6) Eric Hughes [(b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Karen Lynn Price [(b) (6) LaVange, Lisa M [(b) (6) Sandeep Menon [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; William Erhardt [(b) (6) (b) (6) Gelijns, Annetine [(b) (6) Moskowitz, Alan [(b) (6) Ab Babiker [(b) (6) Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr.bios]; Phillips, Andrew [(b) (6) [(b) (6) Birgit Grund [(b) (6) Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.cabr.um]; Joe Koopmeiners [(b) (6) David Vock [(b) (6) Thomas Murray [(b) (6) Max Parmar [(b) (6) Mark Polizzotto [(b) (6) Ginny Kan [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Baker, Jason [(b) (6) Roger Paredes [(b) (6) (b) (6) (b) (6) Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey], (b) (6) (b) (6) Ajay Nirula [(b) (6) Paul Klekotka [(b) (6) (b) (6) Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [(b) (6) Eron, Joseph J Jr [(b) (6) Chew, Kara M.D. [(b) (6) Daar, Eric [(b) (6) Bagiella, Emilia [emilia. (b) (6)]

Subject: ACTIV-3 Writing Team
Attachments: ACTIV_TX-Clinical_ACTIV-3 Writing Team Meeting Agenda_20200615.pdf;
INSIGHT014_ACTIV3_protocol_v0.44_14June2020_PAK_Lilly.docx
Location: https://fnih.zoom.us/ (b) (6)
Start: 6/15/2020 3:00:00 PM
End: 6/15/2020 4:00:00 PM

Required Attendees: Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Reineck, Lora (NIH/NHLBI) [E]; Judy Carrier; Karen Lynn Price; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; (b) (6) Gelijns, Annetine; Moskowitz, Alan; Ab Babiker; Cavan, Reilly; Phillips, Andrew (b) (6) Birgit Grund; Neaton, Jim; Joe Koopmeiners; David Vock; Thomas Murray; Max Parmar; Mark Polizzotto; Ginny Kan; Lane, Cliff (NIH/NIAID) [E]; Baker, Jason; Roger Paredes; (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) Rosenberg, Yves (NIH/NHLBI) [E]; (b) (6)
(b) (6) Ajay Nirula; Paul Klekotka

Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Eron, Joseph J Jr; Chew, Kara M.D.; Daar, Eric; Bagiella, Emilia

Dear ACTIV-3 Writing Team,

Please find the agenda for today's meeting and the current version of the protocol.

Thanks,
Stacey

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Sent: 6/19/2020 12:14:28 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: FW: Action items from 6/17/20 ACTIV Executive Committee Teleconference
Attachments: 6.17.20 ACTIV Executive Committee Meeting Action Items vF.docx

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Thursday, June 18, 2020 9:33 PM
To: Melencio, Cheryl (FNIH) [T] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Pao, William <(b) (6)> Plump, Andrew <(b) (6)> Stoffels, Paul <(b) (6)> Woodcock, Janet (FDA/CDER) <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy <(b) (6)> Hughes, Eric <(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Young, John <(b) (6)> Anderson, James (NIH/OD) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)> Alvarez, Rosa <(b) (6)> Anderson, Margaret <(b) (6)> Chen, Helen <(b) (6)> Elsaid, Olivia <(b) (6)> Gonzalez, Nina <(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Kim, Elizabeth <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Stratton, Ben <(b) (6)> Tolman, Brett <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)> Barasch, Kimberly (NIH/NIAID) [C] <(b) (6)> Conrad, Patricia (NIH/NIAID) [E] <(b) (6)> Dimishkov, Roxanne (NIH/NHLBI) [C] <(b) (6)> McManus, Ayanna (NIH/OD) [E] <(b) (6)> Perala, Mie <(b) (6)> Protasiewicz, Ann <(b) (6)> Riccobene, Kim <(b) (6)> Thomas, Ashley (FDA/CDER) <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> Togashi, Mieko (NIH/NCI) [E] <(b) (6)> Zottoli, Jessica <(b) (6)> Lowy, Douglas (NIH/NCI) [E] <(b) (6)> Lucas Smalldon <(b) (6)>
Subject: Action items from 6/17/20 ACTIV Executive Committee Teleconference
Importance: High

Please see attached the action items from yesterday's ACTIV EC meeting. Please let me know any omissions or corrections. Thanks, David

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/10/2020 1:27:32 AM
To: Jim Neaton [(b) (6)] Jens Lundgren [(b) (6)] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [(b) (6)] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Srinivasan, Badhri [(b) (6)] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Tierney, John (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61553b35beb7479789a06defda628627-jtierney]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [(b) (6)] William Erhardt [(b) (6)] Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; wesley.self@vumc.org; Gelijns, Annetine [(b) (6)] Mark Polizzotto [(b) (6)] Ginny Kan [(b) (6)] Baker, Jason [(b) (6)] Roger Paredes [(b) (6)] Thompson, Taylor, M.D. [(b) (6)] Babiker, Ab [a. (b) (6)]
CC: Chen, Helen Q. [(b) (6)] Wachtel, Jonathan [(b) (6)] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Desrosiers, Elizabeth A. [(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Kenny, Dermot [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Pett, Sarah [(b) (6)] Grace, Beth (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75f1e9e678842258cf6472505f68cd8-bgrace]; Barrett, Kevin (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0490b8cf48984327b737d027f4fddd81-barrett2]; Denning, Eileen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc3c18df3b7945bda704a01abd12b3b4-eileen.ccb]r]
Subject: Follow-up on ACTIV-3 Operations Team Meeting
Attachments: ACTIV_Therapeutics-Clinical_Master Protocol Subgroup_ACTIV-3 Operations Team Meeting_20200609.pdf

Dear ACTIV-3 Operations Team,

Please find attached the notes for the meeting today. Let me know if you have any additions or amendments. Jim just keep me posted on how we can help in the coordination between the networks.

Thanks,

APAR0000005197-2515141

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:21:21 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6) Karen Lynn Price [(b) (6) Pamela Tenaerts, M.D. [(b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [(b) (6) Beumont-Mauviel, Maria [JRDUS] [(b) (6) Peeters, Monika [JRDBE] [(b) (6) Woodfall, Brian [JRDUS] [(b) (6) Van Heeswijk, Rolf [JRDBE] [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #20
Location: <https://fnih.zoom.us/> (b) (6)
Start: 5/22/2020 6:00:00 PM
End: 5/22/2020 7:00:00 PM
Show Time As: Tentative

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/28/2020 10:14:06 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Canceled: ACTIV TX-Clinical Master Protocol Subgroup Meeting #12
Location: <https://fnih.zoom.us/> (b) (6)
Start: 4/30/2020 4:00:00 PM
End: 4/30/2020 5:00:00 PM
Show Time As: Free

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylvia (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Hi TX-Clinical MPSG,

I am canceling our zoom because we will be using Karen's group's zoom.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/23/2020 1:23:29 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6) Karen Lynn Price [(b) (6) Pamela Tenaerts, M.D. [(b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [(b) (6) Beumont-Mauviel, Maria [JRDUS] [(b) (6) .com]; Peeters, Monika [JRDBE] [(b) (6) Woodfall, Brian [JRDUS] [(b) (6) Van Heeswijk, Rolf [JRDBE] [(b) (6) Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Bharucha_David [(b) (6) Gavin, Brian [(b) (6) Sadeh, Jonathan [(b) (6) Harler, Mary Beth [(b) (6)]
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Melsheimer, Rich [CNTNL] [(b) (6)]
Subject: Follow-up to ACTIV TX-Clinical Master Protocol Subgroup Meeting #20
Attachments: ACTIV_Therapeutics-Clinical_Master Protocol Subgroup_22May2020_Meeting Notes.pdf

Dear ACTIV TX-Clinical Master Protocol Subgroup,

Please find the summary of today's call. If you have any additions or amendments, please feel free to send them to me.

As the action items articulate, I will be reaching out to the companies and a few MPSG members to arrange writing team meetings next week. Please let me know if you would like to be on that team.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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Sent: 5/16/2020 9:58:35 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6) Karen Lynn Price [(b) (6) Pamela Tenaerts, M.D. [(b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [(b) (6) Beumont-Mauviel, Maria [JRDUS] [(b) (6) .com]; Peeters, Monika [JRDBE] [(b) (6) Woodfall, Brian [JRDUS] [(b) (6) Van Heeswijk, Rolf [JRDBE] [(b) (6)]
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Follow-up to ACTIV TX-Clinical Master Protocol Subgroup Meeting #17
Attachments: ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 15May2020_Key Takeaways.pdf

Dear ACTIV TX-Clinical Master Protocol Subgroup,

Please find attached the action items and summary notes for yesterday's meeting. Please let us know if you have any additions or amendments.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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Sent: 5/15/2020 4:54:29 PM
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CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #17
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_15May2020 Meeting Guide.pdf
Location: <https://fnih.zoom.us/> (b) (6)
Start: 5/15/2020 5:00:00 PM
End: 5/15/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/2/2020 2:45:51 PM
To: Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [(b) (6)]; Amanda Peppercorn [(b) (6)]; Breuer, Sebastian [(b) (6)]; Martin, Flavius [(b) (6)]; Andrew Charles Adams [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Tressler, Randall (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c1978dd53134e13ac736758e8b8756f-tresslerl]; Smith, David [(b) (6)]; Jacqueline Kirchner [(b) (6)]
CC: [(b) (6)]; Chen, Helen Q. [(b) (6)]; Payton, Natalie [(b) (6)]; Andrew Para [(b) (6)]; [(b) (6)]; Dana Carluccio [(b) (6)]; Lucas Smalldon [(b) (6)]; Rose Li Central Account [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Materials for ACTIV TX-Clinical Agent Prioritization - mAb Subteam Meeting
Attachments: ACTIV_TX-Clinical_mAb Sub Team Meeting Agenda_20200602.pdf; Gating Criteria for SARS CoV 2 mAbs moving into Phase II studies 052820.docx; ITPP COVID-19 mAb PREP PEP __Exec Summ.docx

Dear ACTIV Agent Prioritization – mAb Subteam,

Please find attached the materials for today's meeting, which is confirmed.

1. Meeting agenda
2. Current list of mAb Criteria generated by this team
3. A document shared with us by the Gates team about their considerations for mAb for prophylaxis

A representative from Gates will be joining us today, and if we have time at the end we can discuss there effort a bit. However, the main focus of this meeting will be to address the feedback that was shared with this team from the TX-Clinical Working Group from their meeting last week, which is mainly to reduce and refine the criteria to the minimal necessary mAb to enter a Phase 2 trial.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [(b) (6)] | Mobile: [(b) (6)]

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Sent: 5/14/2020 12:13:17 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Hughes, Eric [(b) (6) Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish (b) (6) ; Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proshan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) ; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [(b) (6) Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
 (b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6)
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose
 Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas
 Smalldon [(b) (6) Stratton, Benjamin [(b) (6)
 (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]

Subject: ACTIV TX-Clinical Working Group #6
Attachments: FDA Guidance on COVID Trials.pdf; ACTIV Therapeutics-Clinical Full Working Group_14May2020 Meeting Guide.pdf
Location: <https://fnih.zoom.us/> (b) (6)

Start: 5/14/2020 6:00:00 PM
End: 5/14/2020 7:00:00 PM
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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschian, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]
Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6)

Dear TX-Clinical Working Group,

Please find attached the slides for tomorrow's call to help facilitate our report outs from both groups. If you have any additions or amendments to propose, please send them to me.

The co-chairs will be updating the group on the ACTIV Executive Committee's feedback and promised actions in response to our letter. This will include some immediate next steps for our group on the mAbs master protocol discussion. Thank you all once again for this feedback to the leadership. It was well received, and it looks like will elicit immediate action on some of the requests.

In addition, please find attached the FDA Guidance for COVID-19 trials that was released today. You can also find it at this link if needed: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-developing-drugs-and-biological-products-treatment-or-prevention>

Looking forward to tomorrow's call.

Thanks,
Stacey

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Sent: 4/30/2020 11:10:54 PM
To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6) .com]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; (b) (6) ; (b) (6) ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcbf32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)
Attachments: Thromboinflammation JTH Ed 041720.pdf; Thromboinflammation Blood-2018-11-882993.full.pdf; C19 Coagulopathy BLOOD 042720.pdf; Immunohemostasis 2017 v032920.pdf

Hi All,

This is the second email. It has the anticoag information.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Adam, Stacey (FNIH) [T]
Sent: Thursday, April 30, 2020 7:05 PM

APAR0000005565-2515152

Subject: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

Importance: High

Dear TX-Clinical Agent Prioritization Subgroup,

I appreciate the candid and productive meeting that we had today. All your feedback is very helpful to refine our process for the next time.

For all of you working on scoring right now, please find attached a number of pieces of information that maybe helpful. Some if this some of your groups may have received before, however, I wanted to share it with the whole group for transparency and for having all of our reference data in one place. The information you will find attached is:

1. The summary spreadsheets for the agents in the host targeted category that have been added from the R&D Consortium group + 1 for Firazyr as it was requested. (one note, the group shared with us Firazyr is likely be tested in a few other trials, so that may need to be considered)
2. Articles on the evolving thrombosis issue that doctors are trying to deal with on the front lines. These were previously shared with the Symptomatic/Supportive therapy group.
3. An article relevant to immune modulator use in COVID-19.
4. Articles for the Antiviral group on some preclinical testing work.
5. Also for the antiviral group, the TX-Preclinical team also just sent this link with access to more screening data, which should contain all but EIDD-2801.
 - a. *"All of these compounds except EIDD-2801 are part of the ReFrame library and have been tested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the ReFrame database here <https://reframedb.org/assays/A00440>. You can create an account for free and search the data."*

Please find attached the updated spreadsheet with all the new relevant compounds added for the groups to vote on. These new compounds for your groups are highlighted in green.

Finally, please find below the captured action items and key takeaways from the meeting.

Action Items

Action Items		
	Information	POC
1	Provide Review Committee members with 5 compounds for review, along with factsheets from the R&D Consortium	Keith Gottesdiener & Elliott Levy / Stacey Adam
2	Send updated score sheets	Stacey Adam
3	Agent Prioritization Review Committee members (immunomodulators) score additional agents that have been added from the R&D Consortium list	AP Sub Group Members
4	Getting standardized, reliable data on the agents • Trans-NIH information, intramural and extramural • Mike Poole, Gates Foundation	Stacey Adam / Ruxandra Draghia-Akli
5	Ask Preclinical Working Group (R&D members) for relevant data on agents if available	Joe Menetski
6	Get data on antivirals from NIAID and NCATS	Sarah Read/Christine Colvis

Key Takeaways

- We are re-evaluating our list for scoring and adding other agents that were inadvertently left out
- We will not go back and re-evaluate the triage list.
- Sub Group Members voicing concern on lack of confidence in agents they've had to score. More research needed on drugs to understand whether these are worth putting into clinical trials. Need for more data.
- Suggested need to understand value of the agents we are evaluating over remdesivir.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks,
Stacey

Stacey J. Adam, PhD
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To: Butters, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Mellors, John W (b) (6) Proschan, Michael (NIH/NIAID) [E] (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Draghia-Akli, Ruxandra (b) (6) Butters, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Eisner, Mark

[(b) (6) Gottesdiener, Keith [(b) (6) Judy Currier
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth
 [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364];
 Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange
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 Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike
 [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
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 [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E]
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 (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Melencio, Cheryl (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Stratton, Benjamin [(b) (6) Qashu, Felicia (NIH/OD) [E]
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 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
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 [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
 Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
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 [(b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6)
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
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 Li Central Account [(b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative
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 [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; jennifer.j. [(b) (6) Mollica, Linda /US
 [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen Q.
 [(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E]
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]

Subject: Canceled: ACTIV Therapeutics-Clinical Working Group Meeting

Start: 8/20/2020 5:00:00 PM

End: 8/20/2020 6:00:00 PM

Show Time As: Free

Recurrence: (none)

Required Attendees: Draghia-Akli, Ruxandra; Butterson, Joan; Hughes, Eric; Bozzette, Sam (NIH/NCATS) [E]; De Claro, R. Angelo (FDA/CDER); Eisner, Mark; Gottesdiener, Keith; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]

Dear ACTIV TX-Clinical WG,

we were unable to find a suitable time to reschedule this week's meeting for to accommodate our presenters. Therefore, we will just cancel for this week. Please enjoy the neutralizing Ab Summit on Thursday!

Thanks,
Stacey

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 6/10/2020 9:08:03 AM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
Subject: Fwd: Agenda and materials for the Protective Immune Responses Sub-Group meeting
Attachments: image001.jpg; ATT00001.htm; image002.jpg; ATT00002.htm; image003.jpg; ATT00003.htm; image004.jpg; ATT00004.htm; Assay WG Tracker _ Updated 6-4.xlsx; ATT00005.htm

Forwarding the information for the vaccines subgroup meeting taking place at 2:30pm today "inter-comparability of immunogenicity assays and centralized labs" and follow up conversations with Janet next week on assay development by vaccine developers — FYI.

Seems there are already POCs for NIAID.

Best,
Ashley

Begin forwarded message:

From: "Santos, Michael (FNIH) [T]" (b) (6)
Date: June 9, 2020 at 10:59:53 PM EDT
To: " (b) (6) "
< (b) (6) >
(b) (6) , "Gruber, Marion (FDA/CBER)"
(b) (6) , "Marks, Peter (FDA/CBER)" (b) (6)
, "Arvin, Ann" (b) (6)
< (b) (6) , Nelson Michael (b) (6) >, "Bett, Andrew J"
(b) (6) , "Gilbert PhD, Peter B" (b) (6) "Kathleen Neuzil"
(b) (6) >, "Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)"
(b) (6) , "Thornburg, Natalie (CDC/DDID/NCIRD/DVD)" (b) (6)
Greg Glenn < (b) (6) > Cavaleri Marco (b) (6) "Kelly, Beth"
(b) (6)
Cc: "Tolman, Brett" (b) (6)
< (b) (6) >, " (b) (6) < (b) (6) >
(b) (6) >, Jeneffer Haynes (b) (6)
"Menetski, Joseph (FNIH) [T]" (b) (6) >, "Alvarez, Rosa Maria" (b) (6)
"Wholley, David (FNIH) [T]" (b) (6) , "Parker, Ashley (NIH/OD) [E]"
< (b) (6) >, Brian Rosen (b) (6) , Cheryl Keech (b) (6)
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting at 2:30pm ET (11:30am PT / 6:30pm CEST).

APAR0000012474-2515154

Last week we were fortunate to have Marco Cavaleri present and lead a discussion on EMA regulatory pathways. Development of a table of those pathways analogous to the table developed for FDA pathways is underway.

At this meeting we will return to the topics from two weeks ago: (1) reaching out to collect information on potential signals of human immunity and (2) inter-comparability of immunogenicity assays and centralized labs.

Since that meeting Ann and Mark Davis discussed the first topic, and reached out to Dan Rotrosen (Director of the Division of Allergy, Immunology, and Transplantation at NIAID). He is unfortunately unable to join this meeting, but we will discuss the categories of information we would like to collect and the potential process for doing so.

On the second topic, we reached out to Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Wednesday, June 3, 2020 11:30 PM

Subject: Notes from yesterday's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting, and particular thanks to Marco for the excellent presentation and discussion.

Meeting notes are attached, with the meeting materials are embedded. The key action item is developing a table of EMA pathways analogous to the one that we previously developed with Marion's input and review for FDA pathways.

Please reach out with any additions or edits to the notes, questions, or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Monday, June 1, 2020 1:04 PM

Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting tomorrow (Tuesday)

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting tomorrow (Tuesday) at 8am ET (5am PT / 2pm CEST). We are very sorry for the extremely early start PT.

The main agenda item is to discuss EMA and member state regulatory pathways to vaccine use and approval. Marco will lead the discussion. He previously shared a set of presentation slides (re-attached here). We are also re-attaching the table on FDA pathways that we circulated previously.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Thursday, May 28, 2020 12:57 PM

Subject: Notes and next steps from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting. Notes are attached.

There were two key areas for next steps that we identified in the meeting:

- Potential signals of human immunity:
 - Develop specifics of what we are looking for from immunology research
 - Ask the WG and other contacts for suggestions of researchers/organizations worth reaching out to
 - Reach out and collect information and contacts to engage with the WG (in presentations or other formats)
- Inter-comparability of immunogenicity assays / centralized labs
 - Reach out to NIAID to learn more about planned centralized lab capabilities and timing

Ann kindly followed up with an initial set of recommendations for the first area. We'll be following up to develop the list of information that we'd like to gather and to discuss how to prioritize whom we reach out to. We'll reach out to NIAID and report back on the second area.

We think these topics will form the basis for future discussions, but we are also trying to schedule a meeting for a time when we can have a discussion about the EMA regulatory pathways with Marco, to complement the conversations we have had on FDA pathways. We hope to have an invite for that out soon.

As always, please reach out with any additional input on the notes, questions, or suggestions for future directions for this group.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 11:42 PM
Subject: Agenda for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 12:19 AM
Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 19, 2020 8:56 AM
Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

(b) (6) | fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/18/2020 12:17:36 PM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6)]; LaVange, Lisa M [(b) (6)]; Sandeep Menon [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f29042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6)]; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; Eron, Joe [(b) (6)]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]
CC: Demarcus [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Elizabeth Kim [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [(b) (6)]; Eron, Joseph J Jr [(b) (6)]; Smith, David [(b) (6)]; Paul Klekotka [(b) (6)]; Ajay Nirula [(b) (6)]; Chen, Helen Q. [(b) (6)]
Subject: Canceled: HOLD for Potential ACTIV-2 Writing Team Meeting - Review of FDA Comments
Location: <https://fnih.zoom.us/> (b) (6)
Start: 6/18/2020 4:00:00 PM
End: 6/18/2020 5:00:00 PM
Show Time As: Free

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6) Kim, Peter (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Erhardt, William (OS/ASA/OCIO/DCIO-Ops) (CTR)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Chen, Helen Q.

Dear ACTIV-2 Writing Team,

We have not yet received the FDA comments expected this morning. Therefore, in the interest of making best use of everyone's time, we will be working with Davey and Judy to find a time to reschedule over the next couple of days. We will be in touch as soon as we have a time.

Thanks,

Stacey

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From: Eakin, Ann (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DAFBA298C194F9D9BC13C54FE0CF29A-EAKINAE]
Sent: 7/2/2020 1:02:54 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [(b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6) Keith Gottesdiener [(b) (6) Elliott Levy [(b) (6) Wung, Peter /US [(b) (6) Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Alvarez, Rosa Maria [(b) (6) Rose Li [(b) (6) Mark Krystal [(b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Sanderson, Philip (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee2d44e63f2645708a3beb2ea1b280a1-sandersonpe]; Tressler, Randall (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c1978dd53134e13ac736758e8b8756f-tresslerl]; [(b) (6) Dana Carluccio [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Sumit Chanda [(b) (6) Rich Colunno [(b) (6)]; Fisher, Robert (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=706cb01f58ef4042aecc4de5ab72ec1-Robert.Fish]
CC: Chen, Helen Q. [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6) Salathin, Carla [(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Re: Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting

I can make 3:30 but not 3.

From: Adam, Stacey (FNIH) [T] < (b) (6) >
Sent: Wednesday, July 1, 2020 8:59:48 PM
To: Eric Hughes < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Ruxandra Draghia-Akli < (b) (6) > Mellors, John W < (b) (6) > Naimish Patel < (b) (6) > Colvis, Christine (NIH/NCATS) [E] < (b) (6) > Young, John < (b) (6) > Stein, Peter (FDA/CDER) < (b) (6) > Poole, Mike < (b) (6) > Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) > Vincent, Michael < (b) (6) > Keith Gottesdiener < (b) (6) > Elliott Levy < (b) (6) > Wung, Peter /US < (b) (6) > Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) > Higgs, Elizabeth

(NIH/NIAID) [E] (b) (6) Carlos O Garner < (b) (6) Goff, David (NIH/NHLBI) [E]
< (b) (6) Alvarez, Rosa Maria < (b) (6) (b) (6)
< (b) (6) Rose Li < (b) (6) Mark Krystal < (b) (6)
Prabhavathi Fernandes < (b) (6) Diamond, Michael < (b) (6) Sanderson,
Philip (NIH/NCATS) [E] < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Tressler,
Randall (NIH/NIAID) [E] < (b) (6) (b) (6) < (b) (6)
Eakin, Ann (NIH/NIAID) [E] < (b) (6) Young, John < (b) (6) Mellors, John W
< (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) Dana Carluccio
< (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Sumit Chanda
< (b) (6) Colvis, Christine (NIH/NCATS) [E] < (b) (6) (b) (6)
< (b) (6) Draghia Akli, Ruxandra [JRDUS] < (b) (6) Hughes, Eric
< (b) (6) (b) (6) < (b) (6) Rich Colonno
< (b) (6) Fisher, Robert (FDA/OC) < (b) (6)
Cc: Chen, Helen Q. < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Alvarez, Rosa Maria
< (b) (6) Salathin, Carla < (b) (6) (b) (6) < (b) (6)
(b) (6) < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)
Subject: RE: Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting

Dear ACTIV TX-Clinical Agent Prioritization Subgroup and Antiviral Subteam,

While I could not get quorum for the 12-1pm slot for our discussion tomorrow, many of you said you could be available after 3pm. Therefore, could you all let me know if 3-4pm ET tomorrow would work for you to meet?

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

From: Adam, Stacey (FNIH) [T]

Sent: Tuesday, June 30, 2020 10:55 PM

To: Eric Hughes < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Ruxandra Draghia-Akli < (b) (6) John Mellors < (b) (6) Naimish Patel < (b) (6) Colvis, Christine (NIH/NCATS) [E] < (b) (6) Young, John < (b) (6) Stein, Peter (FDA/CDER) < (b) (6) Poole, Mike < (b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) Vincent, Michael < (b) (6) Keith Gottesdiener < (b) (6) Elliott Levy < (b) (6) Wung, Peter /US < (b) (6) Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) Carlos O Garner < (b) (6) Goff, David (NIH/NHLBI) [E] < (b) (6)
Cc: Chen, Helen Q. < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Alvarez, Rosa Maria < (b) (6) Salathin, Carla < (b) (6) GM (b) (6) J (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)
Subject: Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

We would like to have a meeting on Thursday with this team and the Antiviral review subteam to discuss and finalize the Antiviral Subgroup's selections from this latest Wave of prioritization.

Please let me know if you would be able to attend this meeting from 12-1pm ET.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/29/2020 1:28:30 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Hughes, Eric [(b) (6) Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaa06ebd70-parkeras]; Patel, Naimish [(b) (6)]; Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proshan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [(b) (6) Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
[(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
(b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6)
Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [dana.carluccio@roseliassociates.com]; Rose
Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas
Smalldon [(b) (6) Stratton, Benjamin [(b) (6)
(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B.
(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]

Subject: ACTIV TX-Clinical Working Group Meeting #9

Location: [\(b\) \(6\)](https://fnih.zoom.us/j/ (b) (6))

Start: 6/4/2020 5:00:00 PM

End: 6/4/2020 6:00:00 PM

Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6)
Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]
Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]

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US (San Jose)

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Password: (b) (6)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/24/2020 11:29:46 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #13
Location: [\(b\) \(6\)](https://fnih.zoom.us/j/ (b) (6))
Start: 5/1/2020 3:00:00 PM
End: 5/1/2020 4:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylvia (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

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US

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US (Houston)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/16/2020 2:58:42 AM
To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetz]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; (b) (6) ; (b) (6) ; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Dana Carluccio [(b) (6)]; Rose Li Central Account [(b) (6)]
Subject: Second Follow-up from ACTIV TX-Clinical Agent Prioritization Subgroup #10
Attachments: 2020-05-14_TX-Clinical_WG_Agent_Prioritization_Committee_Meeting Summary.pdf; Therapeutic information request form-v8.docx

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the formal summary from the call yesterday.

In addition, I am attaching the most current version of the RFI/Survey. Reminder if you have any suggestions please email me. We could particularly use help on the neutralizing mAbs section.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

APAR0000005399-2515159

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/30/2020 12:54:07 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [(b) (6)] Ruxandra Draghia-Akli [(b) (6)] Naimish Patel [(b) (6)] Colvis, Christine (NIH/NCATS) [E] [(b) (6)] Young, John [(b) (6)] Stein, Peter (FDA/CDER) [(b) (6)] Poole, Mike [(b) (6)] Buchman, Tim (OS/ASPR/BARDA) (CTR) [(b) (6)] Vincent, Michael [(b) (6)] Keith Gottesdiener [(b) (6)] Wung, Peter /US [(b) (6)] Koroshetz, Walter (NIH/NINDS) [E] [(b) (6)] Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6)] Carlos O Garner [(b) (6)] Goff, David (NIH/NHLBI) [E] [(b) (6)] John Mellors [(b) (6)] Elliott Levy [(b) (6)]
CC: Elizabeth Kim [(b) (6)] Menetski, Joseph (FNIH) [T] [(b) (6)] Alvarez, Rosa Maria [(b) (6)] Salathin, Carla [(b) (6)] [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [(b) (6)]; Melencio, Cheryl (FNIH) [T] [(b) (6)] Lucas Smalldon [(b) (6)] Walker, Paula (NIH/NINDS) [E] [(b) (6)] Ward, Jackie (NIH/NINDS) [E] [(b) (6)] [(b) (6)]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #7
Attachments: ACTIV Therapeutics-Clinical_AP Subgroup_4May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting 05May2020 Agenda.pdf
Location: <https://fnih.zoom.us/> [(b) (6)]
Start: 5/5/2020 5:00:00 PM
End: 5/5/2020 6:00:00 PM
Show Time As: Busy

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [(b) (6)] [(b) (6)] Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [(b) (6)]

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for today's meeting. My apologies for the late distribution.

Thanks,
Stacey

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
on behalf of Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
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[(b) (6)]; Lucas Smalldon [(b) (6)] FNIH Central Account
[(b) (6)]

Subject: Materials for July 1 ACTIV Partnership Leadership Call

Attachments: ACTIV Leadership Team Meeting 20200630 FINAL.pptx; 2020-06-03_ACTIV_Leadership_Group_Meeting_Summary
Final.docx; Zoom instructions for July 1 2020 call final_.docx

Dear Colleagues:

Thank you very much for taking time to join Francis Collins, Paul Stoffels, and the rest of our Executive Committee tomorrow, July 1, from 1:00 p.m. – 2:30 p.m. Eastern U.S. time to discuss the progress of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership since our last call on June 3. You should have received a calendar invitation for the teleconference, which FNIH will be hosting. Please contact Cheryl Melencio and Joe Menetski at FNIH if you have any issues preparing for or signing into Zoom for the teleconference (b) (6); or (b) (6).

Attached you will find the following materials for the meeting:

- 1) The PowerPoint slide deck for the meeting, which includes the meeting agenda
- 2) The meeting minutes from our June 3 meeting (previously sent to you on June 4)
- 3) Instructions on how to use the Zoom app to access and participate in the meeting.

We look forward to speaking with you tomorrow and hearing your feedback.

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Regards,

David Wholley

Senior Vice President, Research Partnerships

Foundation for the National Institutes of Health

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/17/2020 12:39:21 PM
To: Jim Neaton [(b) (6)]; Jens Lundgren [(b) (6)]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Karen Lynn Price [(b) (6)]; LaVange, Lisa M [(b) (6)]; Sandeep Menon [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80023e7be2dd4554b54d1604fa60df18-rachel.h.ha]; Erhardt, William (OS/ASA/OCIO/DCIO-Ops) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; [(b) (6)]; Gelijns, Annetine [(b) (6)]; Moskowitz, Alan [(b) (6)]; Ab Babiker [(b) (6)]; Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr.bios]; Phillips, Andrew [(b) (6)]; [(b) (6)]; Birgit Grund [(b) (6)]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.ccbr.um]; Joe Koopmeiners [(b) (6)]; David Vock [(b) (6)]; Thomas Murray [(b) (6)]; Max Parmar [m.parmar@ucl.ac.uk]; Mark Polizzotto [(b) (6)]; Ginny Kan [(b) (6)]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Baker, Jason [(b) (6)]; Roger Paredes [(b) (6)]; [(b) (6)]; [(b) (6)]; [(b) (6)]; [(b) (6)]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; [(b) (6)]; [(b) (6)]; Ajay Nirula [(b) (6)]; Paul Klekotka [(b) (6)];
CC: Demarcus [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [(b) (6)]; Eron, Joseph J Jr [(b) (6)]; Chew, Kara M.D. [(b) (6)]; Daar, Eric [(b) (6)]; Bagiella, Emilia [(b) (6)]; [(b) (6)]; Lisbeth Jørgensen [(b) (6)];
Subject: ACTIV-3 Writing Team Meeting
Location: <https://fnih.zoom.us/> [(b) (6)]
Start: 6/22/2020 3:00:00 PM
End: 6/22/2020 4:00:00 PM
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Required Attendees: Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Reineck, Lora (NIH/NHLBI) [E]; Judy Carrier; Karen Lynn Price; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; Erhardt, William (OS/ASA/OCIO/DCIO-Ops) (CTR);
(b) (6) Gelijns, Annetine; Moskowitz, Alan; Ab Babiker; Cavan, Reilly; Phillips, Andrew
(b) (6) Birgit Grund; Neaton, Jim; Joe Koopmeiners; David Vock; Thomas Murray; Max Parmar; Mark Polizzotto; Ginny Kan; Lane, Cliff (NIH/NIAID) [E]; Baker, Jason; Roger Paredes; (b) (6)
(b) (6) (b) (6) M (b) (6) (b) (6) Rosenberg, Yves
(NIH/NHLBI) [E]; (b) (6) jessica. (b) (6) Ajay Nirula; Paul Klekotka
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Eron, Joseph J Jr; Chew, Kara M.D.; Daar, Eric; Bagiella, Emilia; (b) (6) : Lisbeth Jørgensen

Stacey Adam is inviting you to a scheduled Zoom meeting.

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From: Patterson, Amy (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AFAD1CA74B3E449D8B4F3191D65BB70F-PATTERSA]
Sent: 9/9/2020 7:15:55 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Ashley,
Great! We already sent the updates to Helen.
All the Best,
Amy

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, September 9, 2020 3:01 PM
To: Patterson, Amy (NIH/NHLBI) [E] <(b) (6)>
Cc: Chen, Helen Q. (b) (6); Adam, Stacey (FNIH) [T] <(b) (6)> Brodd, Lauren (NIH/OD) [E] <(b) (6)>
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Amy,

We are happy to include any additional trials NHLBI would like to be included. Chris Austin's team at NCATS sent a NIH wide data call (maybe 2 months ago) to request ICS submit planned and ongoing COVID-19 trials -- we used this collective information for the NIH trials.

The Tx clinical WG has requested to review after this was presented to the ACTIV leadership team 2 weeks ago. Stacey and Helen will collect all of the additions/edits and the OD team will make those changes. We will also continue to update the matrix as trials continue to launch.

Thanks,
Ashley

-----Original Message-----

From: Patterson, Amy (NIH/NHLBI) [E] <(b) (6)>
Sent: Wednesday, September 9, 2020 2:50 PM
To: Chen, Helen Q. <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Bozzette, Sam (NIH/NCATS) [E] <(b) (6)> Butters, Joan <(b) (6)> De Claro, R. Angelo (FDA/CDER) <(b) (6)> Draghia-Akli, Ruxandra <(b) (6)> Eisner, Mark <(b) (6)> Gottesdiener, Keith <(b) (6)> Eric Hughes <(b) (6)> Judy Currier <(b) (6)> Kim, Elizabeth <(b) (6)> LaVange, Lisa <(b) (6)> Levv, Elliot <(b) (6)> Mellors, John W <jwm1@pitt.edu>: Menon, Sandeep <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Patel, Naimish <(b) (6)> Peppercorn, Amanda <(b) (6)> Poole, Mike <(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Shen, Yuan Li (FDA/CDER) <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Buchman, Tim (OS/ASPR/BARDA) (CTR) <(b) (6)> Collins, Sylvia (FDA/CDER) <(b) (6)> Higgs, Amanda Peppercorn <(b) (6)> Garner, Carl <(b) (6)> Koroshetz, Walter (NIH/NINDS) [E] <(b) (6)> Timothy Burgess <(b) (6)> Reineck, Lora (NIH/NHLBI) [E] <(b) (6)> Aggarwal, Neil (NIH/NHLBI) [E] <(b) (6)> Rosenberga, Yves (NIH/NHLBI) [E] <(b) (6)> Goff, David (NIH/NHLBI) [E] <(b) (6)> Brown, Jeremy (NIH/NINDS) [E] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)> Jacqueline Kirchner <(b) (6)> Phillips, L <(b) (6)> Beigel, John (NIH) [E] <(b) (6)> Revell CIV DTRA RD (USA) <(b) (6)> Petrovick, Martha - 0449 - MITLL <(b) (6)> Sizemore, Christine (NIH/FIC) [E] <(b) (6)>
Cc: Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy <(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Young, John <(b) (6)> Blass, Mary <(b) (6)> Butcher, Tina <(b) (6)> Demarcus <(b) (6)> Macone, Erin <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)>

< (b) (6) Salathin, Carla < (b) (6) Tountas, Karen (FNIH) [T]
< (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) James, Stephanie (FNIH) [T]
< (b) (6) Wachtel, Jonathan < (b) (6) btolman < (b) (6) Alvarez,
Rosa Maria < (b) (6) >: Gonzalez, Nina < (b) (6) Dana Carluccio
< (b) (6) Rose Li Central Account < (b) (6) >: Margaret
Anderson < (b) (6) Lucas Smalldon < (b) (6) Stratton,
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< (b) (6) Qashu, Felicia (NIH/OD) [E] < (b) (6) Rubin, Daniel B.
(FDA/CDER) < (b) (6) ; Marston, Hilary (NIH/NIAID) [E] < (b) (6) Wung,
Peter /US < (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] < (b) (6) Groesch, Mary
(NIH/NHLBI) [E] < (b) (6) Shipp, Allan (NIH/NHLBI) [E] < (b) (6) Kindzelski,
Andrei (NIH/NHLBI) [E] < (b) (6) Hone, David M (Dave) CIV DTRA J9 (USA)
<david.m. < (b) (6) >: Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)
< (b) (6) Freire, Maria (FNIH) [T] < (b) (6) Elsaid, Olivia
< (b) (6) Appell, Evan < (b) (6)
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Helen,
Thanks for developing this helpful chart. Two of the NHLBI trials are not on the chart - will try to send you the info later today.
Amy

-----Original Message-----

From: Chen, Helen Q. < (b) (6)
Sent: Wednesday, September 9, 2020 1:27 PM
To: Adam, Stacey (FNIH) [T] < (b) (6) Bozzette, Sam (NIH/NCATS) [E] < (b) (6) :
Butterton, Joan < (b) (6) De Claro, R. Angelo (FDA/CDER) < (b) (6)
Drachia-Akli, Ruxandra < (b) (6) Eisner, Mark < (b) (6) >: Gottesdiener, Keith
< (b) (6) Eric Hughes < (b) (6) >: Judy Currier
< (b) (6) >: Kim, Elizabeth < (b) (6) >: LaVange, Lisa < (b) (6) ;
Levv, Elliot < (b) (6) Mellors, John W < (b) (6) Menon, Sandeep
< (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Patel, Naimish
< (b) (6) >: Peppercorn, Amanda < (b) (6) Poole, Mike
< (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah
(NIH/NIAID) [E] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Shen, Yuan Li
(FDA/CDER) < (b) (6) Stein, Peter (FDA/CDER) <Peter.Stein@tda.hhs.gov>: Wholley, David
(FNIH) [T] < (b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) Collins, Sylva
(FDA/CDER) < (b) (6) .gov>; Amanda Peppercorn < (b) (6) Garner, Carl
< (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) Koroshetz, Walter
(NIH/NINDS) [E] < (b) (6) Timothy Burgess < (b) (6) Reineck, Lora
(NIH/NHLBI) [E] < (b) (6) Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6)
Rosenberg, Yves (NIH/NHLBI) [E] < (b) (6) Goff, David (NIH/NHLBI) [E]
< (b) (6) Brown, Jeremy (NIH/NINDS) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E]
< (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6) Jacqueline Kirchner
< (b) (6) Beidel, John (NIH) [E] < (b) (6) Phillips, L
Revell CIV DTRA RD (USA) < (b) (6) Petrovick, Martha - 0449 - MITLL
< (b) (6) Sizemore, Christine (NIH/FIC) [E]
< (b) (6)
Cc: Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy
< (b) (6) Jansen, Kathrin < (b) (6) >: Kurilla, Michael
(NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI) < (b) (6) >: Youn, John
< (b) (6) Biggs, Mary < (b) (6) Butcher, Tina < (b) (6)
Demarcus < (b) (6) Macone, Erin < (b) (6) Melencio, Cheryl (FNIH) [T]
< (b) (6) Salathin, Carla <carla.salathin@novartis.com>: Tountas, Karen (FNIH) [T]
< (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) James, Stephanie (FNIH) [T]
< (b) (6) Wachtel, Jonathan < (b) (6) btolman < (b) (6) Alvarez,
Rosa Maria < (b) (6) Gonzalez, Nina < (b) (6) Dana Carluccio
< (b) (6) >: Rose Li Central Account < (b) (6) >: Margaret
Anderson < (b) (6) >: Lucas Smalldon < (b) (6) Stratton,
Benjamin < (b) (6) Mollica, Linda /US
<Linda. < (b) (6) Qashu, Felicia (NIH/OD) [E] <felicia.qashu@nih.gov>; Patterson, Amy
(NIH/NHLBI) [E] < (b) (6) >: Rubin, Daniel B. (FDA/CDER) < (b) (6) Marston,
Hilary (NIH/NIAID) [E] < (b) (6) Wung, Peter /US < (b) (6) Hoots, W. Keith
(NIH/NHLBI) [E] < (b) (6) >: Groesch, Mary (NIH/NHLBI) [E] <mary. < (b) (6) Shipp,
Allan (NIH/NHLBI) [E] <allan. < (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E]
< (b) (6) Hone, David M (Dave) CIV DTRA J9 (USA) < (b) (6)
Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) < (b) (6) >: Freire, Maria (FNIH)
[T] < (b) (6) >: Elsaid, Olivia < (b) (6) Appell, Evan < (b) (6)
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Dear ACTIV TX-Clinical Working Group Members,

As we have discussed previously, NIH has developed a table to summarize ACTIV and other NIH-supported COVID-19 trials. The goal of the table is to be informative to ACTIV and NIH leadership and to be shared more broadly once the information within it is public.

We would appreciate your review of this draft version of the table, which we are sharing ahead of tomorrow's Working Group meeting. Please do not share the table or the information in it further. We are looking forward to your input.

Warm regards,
Stacey, Mike, and Helen

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Wednesday, June 17, 2020 8:48 AM
To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revel CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]
Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, September 10, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom.us/j/9415086> (b) (6)

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APAR0000005067-2515163

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/5/2020 4:02:38 PM
To: Eric Hughes [(b) (6)] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)] Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)] Keith Gottesdiener [(b) (6)] Elliott Levy [(b) (6)] Wung, Peter /US [(b) (6)] Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)] Salathin, Carla [(b) (6)] [(b) (6)] [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)] Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #7
Attachments: ACTIV Therapeutics-Clinical_AP Subgroup_4May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting 05May2020 Agenda.pdf
Location: <https://fnih.zoom.us/j/91811500000> [(b) (6)]
Start: 5/5/2020 5:00:00 PM
End: 5/5/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; [(b) (6)] [(b) (6)] Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] [(b) (6)]

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for today's meeting. My apologies for the late distribution.

Thanks,
Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/11/2020 7:52:02 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Sandeep Menon [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6) (b) (6) (b) (6) ; Eron, Joe (b) (6) Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]
CC: Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [(b) (6) Eron, Joseph J Jr [(b) (6) Smith, David [(b) (6) Paul Klekotka [(b) (6) Ajay Nirula [(b) (6) Chen, Helen Q. [(b) (6)
Subject: Canceled: HOLD for Potential ACTIV-2 Writing Team Meeting - Review of FDA Comments
Location: [https://fnih.zoom. \(b\) \(6\)](https://fnih.zoom. (b) (6))
Start: 6/18/2020 4:00:00 PM
End: 6/18/2020 5:00:00 PM
Show Time As: Free

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6) Kim, Peter (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Erhardt, William (OS/ASA/OCIO/DCIO-Ops) (CTR)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Chen, Helen Q.

Dear ACTIV-2 Writing Team,

We have not yet received the FDA comments expected this morning. Therefore, in the interest of making best use of everyone's time, we will be working with Davey and Judy to find a time to reschedule over the next couple of days. We will be in touch as soon as we have a time.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/14/2020 12:12:53 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Hughes, Eric [(b) (6) Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish (b) (6) ; Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proshan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [(b) (6) Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rozenbey]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
 (b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6)
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose
 Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas
 Smalldon [(b) (6) Stratton, Benjamin [(b) (6)
 (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]

Subject: Materials for ACTIV TX-Clinical Working Group #6

Attachments: FDA Guidance on COVID Trials.pdf; ACTIV Therapeutics-Clinical Full Working Group_14May2020 Meeting Guide.pdf

Dear TX-Clinical Working Group,

Please find attached the slides for tomorrow's call to help facilitate our report outs from both groups. If you have any additions or amendments to propose, please send them to me.

The co-chairs will be updating the group on the ACTIV Executive Committee's feedback and promised actions in response to our letter. This will include some immediate next steps for our group on the mAbs master protocol discussion. Thank you all once again for this feedback to the leadership. It was well received, and it looks like will elicit immediate action on some of the requests.

In addition, please find attached the FDA Guidance for COVID-19 trials that was released today. You can also find it at this link if needed: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-developing-drugs-and-biological-products-treatment-or-prevention>

Looking forward to tomorrow's call.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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From: Bozzette, Sam (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85F05A3619CF47C7AE39D7BCF0AAC88D-BOZZETTESAA]
Sent: 4/30/2020 2:54:21 PM
To: 'Levy, Elliott' [(b) (6)] LaVange, Lisa M [(b) (6)] Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fdi]; Mark Eisner [(b) (6)] Keith Gottesdiener [(b) (6)] Eric Hughes [(b) (6)] Sandeep Menon [(b) (6)] Amanda Peppercorn [(b) (6)] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6)] Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fdi]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fdi]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fdi]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fdi]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6)]
CC: Mary Biggs [(b) (6)] DeMarcus, Forrest [(b) (6)] Maccone, Erin [(b) (6)] Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)] Elizabeth Kim [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6)] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [(b) (6)] Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Stratton, Benjamin [(b) (6)]
Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Elliot:

Re your first sentence – what about studies of other antivirals? Wouldn't we be looking at a remdesivir control arm and *maybe* a non-inferiority design

From: Levy, Elliott < (b) (6) >
Sent: Thursday, April 30, 2020 10:24 AM
To: LaVange, Lisa M < (b) (6) > Adam, Stacey (FNIH) [T] < (b) (6) > Bozzette, Sam (NIH/NCATS) [E] < (b) (6) > Butterson, Joan < (b) (6) > Collins, Sylva (FDA/CDER)

< (b) (6) Judy Currier < (b) (6) De Claro, R. Angelo (FDA/CDER)
 < (b) (6) Mark Eisner < (b) (6) Keith Gottesdiener
 < (b) (6) Eric Hughes < (b) (6) Sandeep Menon
 < (b) (6) Amanda Peppercorn < (b) (6) Proschan, Michael
 (NIH/NIAID) [E] < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Amanda Peppercorn
 < (b) (6) Price, Dionne (FDA/CDER) < (b) (6) Rubin, Daniel B.
 (FDA/CDER) < (b) (6) Shen, Yuan Li (FDA/CDER) < (b) (6) Farley, John
 (FDA/CDER) < (b) (6) Goff, David (NIH/NHLBI) [E] < (b) (6) Vincent, Michael
 <Michael. (b) (6)
Cc: Mary Biggs < (b) (6) DeMarcus, Forrest < (b) (6) Macone, Erin
 < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan < (b) (6)
 Elizabeth Kim < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Butcher, Tina
 < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Melencio, Cheryl (FNIH) [T]
 < (b) (6) Wung, Peter /US < (b) (6) Qashu, Felicia (NIH/OD) [E]
 < (b) (6) Stratton, Benjamin < (b) (6)
Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

I agree that remdesivir will need to become background therapy in all treatment arms. This gives us to opportunity to test regimens which target both the virus and the host, which is exciting.

With regard to the target RRR, in my view the emerging data confirm the need to power for 1.25, rather than something larger:

-Remdesivir (a rationally designed therapy) exhibited an effect of 1.31 in ACCT1 on TTR, and a somewhat smaller effect (1.23) in the terminated Chinese trial. These are our best estimates for what a rationally designed therapy can do.

-In ACCT1, an effect of 1.31 was associated with a reduction in duration of hospital stay by 4 days, which would be meaningful from a health care system perspective.

-I would not expect other therapies we test to exhibit a larger effect than remdesivir. They were not designed to address the pathophysiology of COVID-19, about which we know little, and their benefit might be partially attenuated when used in combination with another active agent.

-A smaller effect for the experimental therapy would still be meaningful, if one could infer the combination of experimental therapy + remdesivir had an effect of 1.5 or more.

Elliott

From: LaVange, Lisa M (b) (6)
Sent: Thursday, April 30, 2020 6:50 AM
To: Adam, Stacey (FNIH) [T] (b) (6) >; Bozzette, Sam (NIH/NCATS) [E] (b) (6) >; Butterton, Joan (b) (6) Collins, Sylva (FDA/CDER) (b) (6) Judy Currier
 (b) (6) >; De Claro, R. Angelo (FDA/CDER) ; Mark Eisner
 < (b) (6) Keith Gottesdiener (b) (6) Eric Hughes
 (b) (6) >; Levy, Elliott (b) (6) Sandeep Menon < (b) (6) >;
 Amanda Peppercorn (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) >;
 Read, Sarah (NIH/NIAID) [E] <reads@niaid.nih.gov>; Amanda Peppercorn < (b) (6) Price,
 Dionne (FDA/CDER) < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) Shen, Yuan
 Li (FDA/CDER) < (b) (6) Farley, John (FDA/CDER) (b) (6) >; Goff, David
 (NIH/NHLBI) [E] (b) (6) >; Vincent, Michael (b) (6)
Cc: Mary Biggs < (b) (6) DeMarcus, Forrest (b) (6) ; Macone, Erin
 (b) (6) Tountas, Karen (FNIH) [T] (b) (6) >; Wachtel, Jonathan (b) (6)
 Elizabeth Kim (b) (6) >; Parker, Ashley (NIH/OD) [E] < (b) (6) Butcher, Tina

(b) (6) : Wholley, David (FNIH) [T] (b) (6) Melencio, Cheryl (FNIH) [T]
(b) (6) ; Wung, Peter /US (b) (6) ; Qashu, Felicia (NIH/OD) [E]
(b) (6) Stratton, Benjamin (b) (6) >

Subject: [External] Re: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Agree, thanks for raising this, Sam. There are other implications as well. We may need to revisit the meds we will allow as background therapy, now that we have a true standard of care consistent across all sites. And is the target RRR we want to be powered to detect (1.25) the appropriate target relative to Remdesivir?

Looking forward to talking further later today.

Lisa

From: Adam, Stacey (FNIH) [T] (b) (6)
Sent: Thursday, April 30, 2020 9:44 AM
To: Bozzette, Sam (NIH/NCATS) [E] (b) (6) >; Butterson, Joan (b) (6) : Collins, Sylva (FDA/CDER) (b) (6) : Judy Currier < (b) (6) De Claro, R. Angelo (FDA/CDER) (b) (6) >; Mark Eisner (b) (6) >; Keith Gottesdiener (b) (6) : Eric Hughes < (b) (6) : LaVange, Lisa M < (b) (6) Elliott Levy < (b) (6) Sandeep Menon (b) (6) >; Amanda Peppercorn (: Proschan, Michael (NIH/NIAID) [E] (b) : Read, Sarah (NIH/NIAID) [E] (b) (6) Amanda Peppercorn < (b) (6) Price, Dionne (FDA/CDER) (b) (6) : Rubin, Daniel B. (FDA/CDER) (b) (6) ; Shen, Yuan Li (FDA/CDER) (b) (6) : Farley, John (FDA/CDER) (b) (6) ; Goff, David (NIH/NHLBI) [E] < (b) (6) : Vincent, Michael (b) (6) >
Cc: Mary Biggs < (b) (6) >; DeMarcus, Forrest (b) (6) >; Macone, Erin (b) (6) : Tountas, Karen (FNIH) [T] < (b) (6) : Wachtel, Jonathan (b) (6) >; Elizabeth Kim (b) (6) : Parker, Ashley (NIH/OD) [E] (b) (6) >; Butcher, Tina (b) (6) : Wholley, David (FNIH) [T] (b) (6) Melencio, Cheryl (FNIH) [T] (b) (6) >; Wung, Peter /US (b) (6) >; Qashu, Felicia (NIH/OD) [E] (b) (6) Stratton, Benjamin (b) (6) >
Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Hi Sam,

I think you are correct and we can discuss more today and tomorrow. I am currently trying to figure out what the outreach procedure should be, but I agree it likely needs to sooner rather than later.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Bozzette, Sam (NIH/NCATS) [E] (b) (6) >
Sent: Thursday, April 30, 2020 9:19 AM
To: Adam, Stacey (FNIH) [T] (b) (6) : Butterson, Joan (b) (6) : Collins, Sylva (FDA/CDER) < (b) (6) : Judy Currier (b) (6) : De Claro, R. Angelo (FDA/CDER) (b) (6) >; Mark Eisner (b) (6) : Keith Gottesdiener

(b) (6) >; Eric Hughes < (b) (6) : LaVange, Lisa M < (b) (6)
 Elliott Levy < (b) (6) >; Sandeep Menon (b) (6) : Amanda Peppercorn
 (b) (6) >; Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah
 (NIH/NIAID) [E] (b) (6) ; Amanda Peppercorn < (b) (6) >; Price, Dionne
 (FDA/CDER) < (b) (6) Rubin, Daniel B. (FDA/CDER) (b) (6) >; Shen, Yuan Li
 (FDA/CDER) (b) (6) >; Farley, John (FDA/CDER) (b) (6) ; Goff, David (NIH/NHLBI)
 [E] (b) (6) ; Vincent, Michael < (b) (6)
Cc: Mary Biggs < (b) (6) : Demarcus < (b) (6) >; Macone, Erin < (b) (6)
 Tountas, Karen (FNIH) [T] < (b) (6) : Wachtel, Jonathan (b) (6) : Elizabeth Kim
 (b) (6) >; Parker, Ashley (NIH/OD) [E] (>; Butcher, Tina
 (b) (6) >; Wholley, David (FNIH) [T] (b) (6) ; Melencio, Cheryl (FNIH) [T]
 < (b) (6) : Wung, Peter /US (b) (6) >; Qashu, Felicia (NIH/OD) [E]
 (b) (6) >; Stratton, Benjamin (b) (6) >
Subject: Re: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Good morning all:

It would seem that our active control arm had been identified. Should we get in the queue with Gilead sooner rather than later - or have we already reached out to them?

S

From: "Adam, Stacey (FNIH) [T]" (b) (6)
Date: Thursday, April 23, 2020 at 8:31:00 PM
To: "Bozette, Sam (NIH/NCATS) [E]" (b) (6) , "Butterton, Joan" (b) (6) ,
 "Collins, Sylva (FDA/CDER)" (b) (6) >, "Judy Currier" < (b) (6) , "De Claro, R.
 Angelo (FDA/CDER)" < (b) (6) , "Mark Eisner" < (b) (6) , "Keith Gottesdiener"
 (b) (6) >, "Eric Hughes" (b) (6) >, "LaVange, Lisa M"
 < (b) (6) "Elliott Levy" (b) (6) >, "Sandeep Menon" (b) (6) >,
 "Amanda Peppercorn" < (b) (6) , "Proschan, Michael (NIH/NIAID) [E]"
 (b) (6) , "Read, Sarah (NIH/NIAID) [E]" (b) (6) , "Amanda Peppercorn"
 < (b) (6) , "Price, Dionne (FDA/CDER)" < (b) (6) , "Rubin, Daniel B.
 (FDA/CDER)" (b) (6) , "Shen, Yuan Li (FDA/CDER)" < (b) (6) , "Farley, John
 (FDA/CDER)" (b) (6) , "Goff, David (NIH/NHLBI) [E]" < (b) (6) >, "Vincent, Michael"
 (b) (6) >
Cc: "Mary Biggs" (b) (6) , "Demarcus" (b) (6) >, "Macone, Erin"
 < (b) (6) , "Tountas, Karen (FNIH) [T]" (b) (6) >, "Wachtel, Jonathan"
 (b) (6) >, "Elizabeth Kim" (b) (6) >, "Parker, Ashley (NIH/OD) [E]"
 (b) (6) >, "Butcher, Tina" < (b) (6) , "Wholley, David (FNIH) [T]"
 (b) (6) >, "Melencio, Cheryl (FNIH) [T]" (b) (6) >, "Wung, Peter /US"
 (b) (6) , "Qashu, Felicia (NIH/OD) [E]" (b) (6) , "Stratton, Benjamin"
 (b) (6)
Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for tomorrow's meeting.

1. Agenda
2. Slides for discussion updated with the decisions from today
3. A useful resource about current standard clinical treatment guidelines from the front lines for COVID. This may be a useful resource in selecting how to do minimal data collection and trying to understand SOC.

Please let me know if you have questions or other things you think would be helpful for the group to review.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 10/14/2020 4:16:20 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: Notes from ACTIV Executive Committee Meeting October 7 2020
Attachments: 2020-10-07_Executive_Committee_Meeting_Summary_FINAL.docx

FYI

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Wednesday, October 14, 2020 11:43 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>
Dolsten, Mikael <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Pao, William <(b) (6)>
Plump, Andrew <(b) (6)> Stoffels, Paul <(b) (6)> Woodcock, Janet (FDA/CDER) <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)>
Desrosiers, Betsy <(b) (6)> Eric Hughes <(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)>
Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Young, John <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)> Alvarez, Rosa Maria <(b) (6)> Margaret Anderson <(b) (6)>
Appell, Evan <(b) (6)> Chen, Helen Q. <(b) (6)> Connelly, Sarah <(b) (6)> Gonzalez, Nina <(b) (6)> Hawk, Harrison <(b) (6)>
Mendelson, Jesse <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Sorosa, Alex <(b) (6)> Stratton, Benjamin <(b) (6)>
btolman <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>
Anderson, James (NIH/OD) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)> Carluccio, Dana <(b) (6)>
Castillejos, Carlos <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)> FNIH Central Account <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)>
Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)>
Parker, Ashley (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Gorman, Greta (FNIH) [T] <(b) (6)>
Meltzer, Abbey (FNIH) [T] <(b) (6)>
Subject: Notes from ACTIV Executive Committee Meeting October 7 2020

Dear Executive Committee members and meeting participants,

With apologies for lateness, here are the notes from our ACTIV Executive Committee meeting last week. Please let me know if you have any comments or questions.

Regards,
David Wholley

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnihi.org

APAR0000021108-2515171

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 6/4/2020 4:02:10 PM
To: John Lepore <(b) (6)> Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Invitation for ACTIV Leadership Meeting 6/3
Attachments: ACTIV Leadership Team Meeting 20200603 FINAL.pptx

John, we will make sure you get the action items and meeting notes from yesterday. The presentation slide deck is attached. David

From: John Lepore <(b) (6)>
Sent: Thursday, June 4, 2020 7:53 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)>
Subject: RE: Invitation for ACTIV Leadership Meeting 6/3

Dear Francis-

Thank you for your note. Unfortunately, I did not see it in time to make the meeting earlier today, but I will look forward to joining future meetings.

All best wishes -

John

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Tuesday, June 02, 2020 9:54 PM
To: John Lepore <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)>
Subject: Invitation for ACTIV Leadership Meeting 6/3

EXTERNAL

Dear John,

We greatly appreciate you recommending David Payne, Amanda Peppercorn, and Emmanuel Hanon to serve on the ACTIV therapeutics preclinical, therapeutics clinical, and vaccine working groups. I am following up to invite you to join our ACTIV leadership meetings. These are usually scheduled bimonthly and our next virtual meeting will take place **tomorrow June 3, 12:00-1:30pm**. Apologies for the ridiculously short notice, as I should have extended this invitation previously – but it would be great if you are available to attend and hear an update from our ACTIV working group co-chairs and discuss progress with the leadership team.

I am cc'ing FNIH David Wholley and Cheryl Melencio, please let us know at your earliest convenience if you plan to attend and Cheryl will send you the calendar invitation.

Best wishes, Francis

Francis S. Collins, M.D., Ph.D.
Director, NIH

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 11/1/2020 8:55:15 PM
To: Jens Lundgren (b) (6) Jim Neaton (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Birgit Grund (b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; David Douglas (b) (6) Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Michael Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ecf3e6209774f4e9143192c89ae7471-MichaelHugh]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hochman, Judith (b) (6) Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; (b) (6) (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; LaVange, Lisa M (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; (b) (6) (b) (6) (b) (6) (b) (6) Leifer, Eric (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82f6ef6b63654d1294890664f81c9c95-leifere]; Wa (b) (6) Scott Berry (b) (6) (b) (6) Wright, Clinton (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e18bd48748f4d7dab41338948aa9a59-wrightclb]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=febabc96e8d04b5fa51d5749ad0c74a6-David.Doug]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; (b) (6) (b) (6) Thomas Stock (b) (6) Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Philip, Ritika (b) (6) Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Lawlor, Ciarán

[(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfc346afd7671ee69f-Deydre.Teyh]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Ramakrishnan, Raahul [(b) (6)]

Subject: Follow-up from October ACTIV Cross Trial Meeting

Attachments: 2020-10-30_Cross-Trial_Meeting_Summary.pdf; American Psychologist Final.pdf; COVID-19_Leader_Return_to_Workplace_Quickguide_WRAIR.pdf; Covid-19_Leadership_and_Stress_WRAIR.pdf; COVID-19_Leadership_Steps_Quick-Guide.pdf; Leadership Counts_ Staying Ahead of Stress Promotes Soldier Resilience _AUS.pdf; Tannenbaum, Traylor et al BMJ (in press).pdf; ACTIV_Monthly Cross-Trial Meeting_20201030.pdf

Dear ACTIV-1, -2, -3, -4, and -5 Trial Leads,

Apologies for the second email, but the first was missing the Basecamp link.

Please find attached the follow-up materials from our meeting on Friday.

1. Meeting slides
2. Meeting summary
3. Stress Management Tools and Articles
 - COVID19 Leadership Checklist – Mitigating Team Stress. This is a really simple guide to remind leaders what has the most impact while leading during this pandemic.
 - COVID19 Returning to the Workplace – Leading the Transition. This was designed to help leaders effectively return people to the workplace – but it is also a helpful reminder of the different perspectives people have on the risk/fear of COVID19 and being in the work setting.
 - Army Magazine article – Col. Teyhen's team took these checklists and wrote an article that applies the concepts with a little more text for those that would prefer that media.
 - COVID-19 Leadership Steps Quick Guide – This is the latest tool discussed by Col. Teyhen on Friday.
 - American Psychologist article
 - BMJ article
4. Link to the Trial Accrual Simulation Tool – All of you should either have or will be receiving an invite from Basecamp to the site.
 - ACTIV Accrual Simulation Model Folder – For ACTIV-1, -4, and -5 Core Teams
 - General Accrual Model

Please let me know if you have any questions. If you would like to have further information on the stress management tools, Col. Teyhen ((b) (6)) can assist. If you have any questions on the accrual simulation tool Helen Chen ((b) (6)) and I, and if you have any amendments to the meeting please let me know.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer

APAR0000022426-2515173

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/5/2020 1:58:10 AM
To: Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Bascles, Lionel [(b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6) Desrosiers, Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6) Srinivasan, Badhri [(b) (6) Wachtel, Jonathan [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot [(b) (6) Anderson, Margaret [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6) Hamilton, Nancy [(b) (6) Minnich, Beth [bminnich@fredhutch.org]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Stratton, Benjamin [(b) (6) Tolman, Brett [(b) (6) Garner, Carlos [(b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich [(b) (6)

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05052020.pdf; Network survey responses 04 May 2020.pdf; Site survey responses 04May2020.pdf; DRAFT CRO survey.docx
Location: <https://zoom.us/> (b) (6)
Start: 5/5/2020 1:00:00 PM
End: 5/5/2020 2:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM
Required Attendees: Stein, Peter (FDA/CDER); Vincent, Mike; Woodcock, Janet (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzone; Resnansky, Laura; Srinivasan, Badhri; Wachtel, Jonathan; Qashu, Felicia
Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Anderson, Margaret; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6) Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6) Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Garner, Carlos; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues,

Attached is the meeting agenda along with current survey results (40 networks and 463 sites to-date!). In addition, attached are draft questions to consider for the CRO survey that will be discussed, but please note that some questions are carried over from the network survey for consideration (editing or deleting). Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

APAR0000006531-2515174

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From: Young, John (b) (6)
Sent: 5/19/2020 12:06:52 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Alvarez, Rosa Maria [(b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Carlos O Garner [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Elizabeth Kim [(b) (6) Elliott Levy [(b) (6) Eric Hughes [(b) (6) (b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; (b) (6) Keith Gottesdiener [(b) (6) Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Lucas Smalldon [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Naimish Patel [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Poole, Mike [(b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Rose Li Central Account [(b) (6) Ruxandra Draghia-Akli [(b) (6) Salathin, Carla (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Michael [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Wung, Peter /US [(b) (6)
Subject: Re: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #11

Hi Stacey

Thanks for sharing the materials. Some additional points of consideration for the SARS-CoV-2 neutralizing antibodies:

- epitope conservation amongst geographical isolates
- specific for SARS-CoV-2 or broader efficacy against SARS and other corona viruses (e.g. bat coronaviruses)?
- heavy chain modifications and effector functions
- neutralizing activity in cellular infection assays

Best regards

John

On Tue, 19 May 2020 at 04:24, Adam, Stacey (FNIH) [T] < (b) (6) > wrote:

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for tomorrow's call.

1. Slides with topics and agenda internal.
2. Updated Company RFI/Survey for final review.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/7/2020 1:38:40 AM
To: Eric Hughes [(b) (6)] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)] Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)] Keith Gottesdiener [(b) (6)] Elliott Levy [(b) (6)] Wung, Peter /US [(b) (6)] Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetz]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)] Salathin, Carla [(b) (6)] [(b) (6)] [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)] Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: Materials for ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #8
Attachments: ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting 07May2020 Agenda.pdf; ACTIV Therapeutics-Clinical_AP Subgroup_7May2020 Meeting Guide.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

We are looking forward to our meeting tomorrow during which we will work to flesh out some of our suggestions for improvements in the prioritization process a bit more. We will also talk about next steps over the rest of this week and next.

Please find attached the agenda and slides for tomorrow's meeting. If you have any additions or amendments, please let me know.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/28/2020 1:20:01 AM
To: Eric Hughes [(b) (6)] Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)] Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)] Wung, Peter /US [(b) (6)] Keith Gottesdiener [(b) (6)] Elliott Levy [(b) (6)] Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]
CC: Elizabeth Kim [(b) (6)] Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)] Salathin, Carla [(b) (6)] [(b) (6)] [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]
Subject: Reminder of Triage Reports Due and Agenda for ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting Tomorrow
Attachments: ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting Agenda_04282020.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached our proposed agenda for tomorrow's APSG call. This agenda currently assumes that all will be able to finalize your triage of the initial list of agents by 9 am EDT tomorrow. If we do not have all of the triage reports, we will discuss a revised agenda.

With that in mind, please remember that if at all possible, and knowing that this is a fast turnaround, we would like to have your triage reports to Elizabeth and I by 9am EDT tomorrow (Tuesday, April 28). Please also let us know if you cannot find the email from this weekend, and I will resend with all the materials.

Thanks in advance for all the work that you are doing and thanks to those who have already sent your reports.

Best,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 8/26/2020 11:43:16 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]
Subject: RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Ashley suggested that since the current version of the checkerboard is 1) still not fully vetted and 2) contains links, it is not put in the deck for distribution for now but instead will be shown as part of the Zoom presentation. We can always send out the full version with dead links or whatever later.

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Tuesday, August 25, 2020 9:53 PM
To: Wholley, David (FNIH) [T] <(b) (6)>
Subject: RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Uh-oh. Where's the checkerboard? I thought that would be inserted after slide 35.

FC

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, August 25, 2020 9:47 PM
To: Austin, Christopher (NIH/NCATS) [E] (b) (6) >; Bancel, Stephane (b) (6) >; Carter, Kara <(b) (6)>; Cavaleri, Marco (b) (6) >; Cihlar, Tomas <(b) (6)>; Collins, Francis (NIH/OD) [E] (b) (6) >; Corey, Larry (b) (6) >; Culp, Michelle (NIH/OD) [E] (b) (6) >; Disbrow, Gary (OS/ASPR/BARDA) (b) (6) >; Dolsten, Mikael (b) (6) >; Erbeling, Emily (NIH/NIAID) [E] (b) (6) >; Erck, Stan (b) (6) >; Fauci, Anthony (NIH/NIAID) [E] (b) (6) >; Freire, Maria (FNIH) [T] (b) (6) >; Gadbois, Ellen (NIH/OD) [E] (b) (6) >; Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)>; Hudson, Thomas <(b) (6)>; James, Stephanie (FNIH) [T] <(b) (6)>; Johnson, Robert (OS/ASPR/BARDA) (b) (6) >; Kramer, Lynn (b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Lepore, John <(b) (6)>; Marks, Peter (FDA/CBER) <(b) (6)>; Marston, Hilary (NIH/NIAID) [E] <(b) (6)>; Mascola, John (NIH/VRC) [E] (b) (6) >; Meeker, David (b) (6) >; Menetski, Joseph (FNIH) [T] (b) (6) >; Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6) >; Pandya, Hitesh <(b) (6)>; Pangalos, Mene (b) (6) >; Pao, William (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) >; Paul, Steve (b) (6) >; Perlmutter, Roger (b) (6) >; Plenge, Robert (b) (6) >; Plump, Andy (b) (6) >; Rachel Ramoni (b) (6) >; Rasi, Guido (b) (6) >; Reed, John (b) (6) >; Reese, David (b) (6) >; Rouse, Doris (b) (6) >; Santos, Michael (FNIH) [T] (b) (6) >; Skovronsky, Daniel (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) >; Stoffels, Paul (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Talley, Michael (b) (6) >; Tsai, John (b) (6) >; Vessey, Rupert <(b) (6)>; Virgin, Skip (b) (6) >; Wholley, David (FNIH) [T] (b) (6) >; Woodcock, Janet (FDA/CDER) (b) (6) >; Young, John (b) (6) >; Colvis, Christine (NIH/NCATS) [E] (b) (6) >

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

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Sent: 5/29/2020 9:58:59 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30
Attachments: Responses to Qs re AC Clinical Trial Strategy 052920 final fsc.docx

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note – has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Friday, May 29, 2020 1:59 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gonzalez, Nina <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a *portfolio* approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
 - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
 - ACTIV hiVIG (sponsored by NIAID) – in progress

- ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
- ACTIV-2* – Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
- ACTIV-3* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
- ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS “Master” Network) – (Phase II/III) – projected launch late June
- ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August *(if needed; i.e. if agents are not incorporated into mAb protocols)*
 * current priority
 [for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
 [Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
 - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
 - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
 - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
 - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
 - Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
 - Protocol is 80% complete
 - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
 - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
 - All three companies have written their sections of the protocols, which are being merged into the master design
 - Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- “ACTIV-4” Protocol for anticoagulants
 - Need bullets from NHLBI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley
 Senior Vice-President, Research Partnerships
 Foundation for the National Institutes of Health

(b) (6)

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Subject: FW: BIO REC Discussion on ACTIV

fyi

From: Edd Fleming <(b) (6)>
Sent: Wednesday, April 29, 2020 7:18 PM
To: Hudson, Thomas J <(b) (6)> Jerel Davis <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>
Cc: Harriet Keane <(b) (6)> Gaurav Agrawal <(b) (6)>
Subject: RE: BIO REC Discussion on ACTIV

Tom – thanks for reaching out.

We are quite open to biotechs/emerging companies as COVID R&D. That is manifesting itself in the following ways

1. We have an open door to the steering committee calls. To date, this has not been used much although open. Alnylam is closest and joined last week.
2. Portal for biotechs to ask for help that flows into the appropriate working groups. This is flowing primarily through the BioCentury portal. This is getting used. I think BC did an email blast bc there have been 12 requests from biotechs in last 2 days as a result that we are working through
3. Informal connections – we are also speaking to biotechs who get connected through someone they know. I would say there are 2-4 of these interactions a week.

Happy to discuss in more detail and to think about how we can be more effective on this front.

Edd

From: Hudson, Thomas J <(b) (6)>
Sent: Wednesday, April 29, 2020 4:13 PM
To: Jerel Davis <(b) (6)>; Edd Fleming <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>
Subject: [EXT]FW: BIO REC Discussion on ACTIV

Hi: I am getting questions from AbbVie representatives on the BIO Regulatory Environment Committee (REC) that emerging companies do not feel included in ACTIV.

I also think that at inception, COVID R&D was interested in tapping into the biotechnology community, but this has not been among the leading initiatives to date.

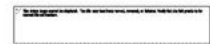
Are there answers that we could provide to REC?

Tom

THOMAS HUDSON
Senior Vice-President, R&D

APAR0000001794-2515181

Chief Scientific Officer



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From: Sorg, Elaine K (b) (6)

Sent: Wednesday, April 29, 2020 11:25 AM

To: Roberts, Khyati N (b) (6); Hudson, Thomas J (b) (6)

Cc: Pacelli, Jaquelin (b) (6); Beard, Binta (b) (6)

Subject: RE: BIO REC Discussion on ACTIV

Khyati,

Thank you for your follow up. I have not seen the meeting minutes yet from the REC, but think you have captured the sentiment from the emerging market companies very well. Amongst the larger companies – including those without a seat at the table in ACTIV, no concerns were expressed.

Regards,
Elaine

ELAINE K. SORG

President, U.S. Immunology



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From: Roberts, Khyati N (b) (6)

Sent: Wednesday, April 29, 2020 11:54 AM

To: Hudson, Thomas J (b) (6)

Cc: Pacelli, Jaquelin (b) (6); Sorg, Elaine K (b) (6); Beard, Binta

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(b) (6)

Subject: BIO REC Discussion on ACTIV

Tom,

We'd like to share with you some concerns that were shared at a recent discussion at the BIO Regulatory Environment Committee (REC) regarding the ACTIV initiative. (Elaine Sorg is our BIO Board/REC Member and represented AbbVie on the call).

Several of the small, emerging companies raised concerns regarding the recently formed on ACTIV PPP. As you may know many of the small companies do not have the resources to join PPP and feel they are being 'left behind' because they are not well represented. They fear that the current industry reps, largely big pharma, may not have their best interest in mind and may agree to stringent controls on clinical trials and procedures that may cause unneeded 'micro-managing' the trials. They are under the impression that if they are not a member of the PPP, a compound they are developing for COVID-19 may not be considered via the process established by ACTIV or be of a lower priority. I think most of this is likely due to the lack of understanding of exactly how the PPP will be developing the roadmap and who the industry experts are that are involved in the discussions. BIO has made some initial contacts with NIH, and will continue its outreach to see how the PPP could be more inclusive/transparent.

I understand the initiative has just begun discussions to develop a roadmap to develop therapies for COVID-19, but we wanted to flag this issue for you as you may wish to raise the issue at the PPP to discuss how best to alleviate the concerns and avoid any potential negative public comments from them. Additionally, if there is any information you think we can share with BIO directly to help alleviate the concerns, please let us know.

Please let me know if you have any questions.

Best regards, Khyati

KHYATI ROBERTS

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Subject: Canceled: ACTIV Preclinical full working group

Location: <https://fnih.zoom.us/> (b) (6)

Start: 1/13/2021 3:00:00 PM

End: 1/13/2021 4:00:00 PM

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Recurrence: Weekly
every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6)
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(b) (6) (b) (6) (b) (6) ; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6) Parker,
Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter
(OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM
USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E];
(b) (6)
Optional Attendees: FNIH; (b) (6) Reynolds, Lindsey; (b) (6) Wholley, David (FNIH)
[T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers,
Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID)
[E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T];
Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael;

Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah; (b) (6).com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd

Starting Every other week meetings. JPM1/8/2021

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Sent: 5/3/2020 7:42:16 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla [(b) (6)]; (b) (6) [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Attachments: Cytochrome_P450_3A4_and_3A5_Known_Drug_Interaction_Chart.pdf

Fyi- drugs affected by CYP3A4
w

From: Adam, Stacey (FNIH) [T] < (b) (6) >
Sent: Sunday, May 3, 2020 2:31 PM
To: Eric Hughes < (b) (6) >; Read, Sarah (NIH/NIAID) [E] < (b) (6) >; Ruxandra Draghia-Akli < (b) (6) >; Mellors, John W < (b) (6) >; Naimish Patel < (b) (6) >; Colvis, Christine (NIH/NCATS) [E] < (b) (6) >; Young, John < (b) (6) >; Stein, Peter (FDA/CDER) < (b) (6) >; Poole, Mike < (b) (6) >; Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) >; Vincent, Michael < (b) (6) >; Keith Gottesdiener < (b) (6) >; Elliott Levy < (b) (6) >; Wung, Peter /US < (b) (6) >; Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) >; Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) >; Carlos O Garner < (b) (6) >
Cc: Elizabeth Kim < (b) (6) >; Menetski, Joseph (FNIH) [T] < (b) (6) >; Salathin, Carla < (b) (6) >; (b) (6) < (b) (6) >; Parker, Ashley (NIH/OD) [E] < (b) (6) >; Wholley, David (FNIH) [T] < (b) (6) >; Melencio, Cheryl (FNIH) [T] < (b) (6) >; Lucas Smalldon < (b) (6) >; Walker, Paula (NIH/NINDS) [E]

< (b) (6) Ward, Jackie (NIH/NINDS) [E] < (b) (6)
Subject: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting

Hi ACTIV TX-Clinical Prioritization Subgroup members,

Please find attached the final tally of scores for the agents that came through triage in Wave 1. We will use this document for our discussions today.

For those who sent me comments, I did not want to over whelm the score sheet with multiple rows of information. However, I have those and I will include them in the final record for posterity for this round. You can also feel free to bring them up during the discussion if helpful to the group.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/25/2020 12:34:25 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [keith. (b) (6) Hughes, Eric [(b) (6) Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaa06ebd70-parkeras]; Patel, Naimish [(b) (6) ; Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [(b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6)

Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6)] Rose Li Central Account [(b) (6)] Anderson, Margaret [(b) (6)] Lucas Smalldon [(b) (6)] Stratton, Benjamin [(b) (6)] Mollica, Linda /US [(b) (6)] Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]

Subject: Follow-up from the ACTIV Therapeutics-Clinical Working Group - Meeting #3

Attachments: ACTIV Therapeutics-Clinical WG 23Apr2020 Meeting Guide 04222020v3.pdf; 2020-04-23_TX-Clinical_WG_Meeting_Summaryv2.pdf

Dear COVID PPP Therapeutics-Clinical WG Members and Co-Chairs from other WGs,

Please find attached the formal summary from yesterday's meeting and some slightly updated slides base on our conversation.

As always please let me know if you have any questions, amendments, or additions to the summary. I look forward to our next week of progress!

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) | Mobile: (b) (6)
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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)

(b) (6)

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6)]; Prabhavathi

Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li
[(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6) Dave Frankowski [(b) (6) antoinette_baric
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy,
Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188];
Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];
Mason, Stephen [(b) (6) (b) (6) Connelly, Sarah
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab];
(b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd
[(b) (6) (b) (6)

Subject: Canceled: ACTIV Preclinical full working group

Start: 12/23/2020 3:00:00 PM

End: 12/23/2020 4:00:00 PM

Show Time As: Free

Recurrence: (none)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Meeting ID: (b) (6)

Passcode: (b) (6)

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 6/3/2020 11:37:25 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Updated Master email list
Attachments: ACTIV Working Group Rosters - MASTER.xlsx

Is this what you want?

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, June 3, 2020 5:59 PM
To: Melencio, Cheryl (FNIH) [T] <(b) (6)>
Subject: RE: Updated Master email list

Thanks, Cheryl! Can I also have the updated spreadsheet that the FNIH COMMs group has with names and titles? No rush.

From: Melencio, Cheryl (FNIH) [T] <(b) (6)>
Sent: Wednesday, June 3, 2020 5:35 PM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: Updated Master email list

Hi Ashley

Here is the spread sheet updated today with David Reese, Tomas Cihlar (who will be attending leadership team meetings for William Lee, Gilead) and Kara Cater added to Industry and master email list. I have also added Tonya Villafana, AstraZeneca to Vaccines Working Group.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 11/12/2020 5:10:22 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aebc9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaafe06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [(b) (6)]; Vessey, Rupert [(b) (6) m]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy

[(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]

CC: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse [(b) (6) asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Bell, Julie [(b) (6)]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Caulfied, Anita [(b) (6) Coan, Amanda [(b) (6)]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan [(b) (6) Fuhrer, Nicole [(b) (6) Giorgi, Sara [(b) (6) Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Krack, Kimberly [kimberly]; [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange

Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel];
Lever, Susan (b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus];
Minnich, Beth (b) (6) Perala, Mie (b) (6) Protasiewicz, Ann
[ann. (b) (6) Riccobene, Kim (b) (6) Riffin, Mary (b) (6)
Ripley, Nadege (b) (6) Schuster, Donna (b) (6) Sepulveda,
Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD)
[C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley
(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Hughes, Karen (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Tajalli, Ada (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]; Togashi, Mieke (NIH/NCI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy
[(b) (6) Zottoli, Jessica (b) (6)

Subject: ACTIV Leadership Team Meeting #11

Location: https://fnih.zoom.us (b) (6)

Start: 12/16/2020 3:00:00 PM

End: 12/16/2020 4:00:00 PM

Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]

Optional Attendees: Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riffin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Hughes, Karen (NIH/OD) [E]; Tajalli, Ada (NIH/OD) [E]; Togashi, Mieke (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

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From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 11/23/2020 5:28:58 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Notes from Thursday's ACTIV Leadership Team Meeting

Thanks!

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Monday, November 23, 2020 11:34 AM
To: Brodd, Lauren (NIH/OD) [E] <(b) (6)>
Subject: FW: Notes from Thursday's ACTIV Leadership Team Meeting

From: Melencio, Cheryl (FNIH) [T] (b) (6) > On Behalf Of Wholley, David (FNIH) [T]
Sent: Monday, November 23, 2020 11:18 AM
To: Austin, Christopher (NIH/NCATS) [E] (b) (6) ; Bancel, Stephane
(b) (6) >; Carter, Kara (b) (6) >; Cavaleri, Marco
<(b) (6) >; Cihlar, Tomas (b) (6) Collins, Francis (NIH/OD) [E]
(b) (6) Corey, Larry (b) (6) ; Culp, Michelle (NIH/OD) [E] (b) (6)
Victoria Davey <(b) (6) >; Disbrow, Gary (OS/ASPR/BARDA) <(b) (6) >; Dolsten, Mikael
(b) (6) >; Erbeling, Emily (NIH/NIAID) [E] (b) (6) >; Erck, Stan
(b) (6) Fauci, Anthony (NIH/NIAID) [E] (b) (6) >; Freire, Maria (FNIH) [T]
(b) (6) Gadbois, Ellen (NIH/OD) [E] (b) (6) >; Gibbons, Gary (NIH/NHLBI) [E]
(b) (6) >; Hudson, Thomas (b) (6) >; James, Stephanie (FNIH) [T]
(b) (6) >; Johnson, Robert (OS/ASPR/BARDA) (b) (6) >; Kramer, Lynn
(b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6) Lepore, John (b) (6) >;
Marks, Peter (FDA/CBER) <(b) (6) >; Marston, Hilary (NIH/NIAID) [E] (b) (6) >;
Mascola, John (NIH/VRC) [E] <(b) (6) >; Meeker, David (b) (6) >; Menetski, Joseph
(FNIH) [T] <(b) (6) >; Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6) >; Pandya, Hitesh
(b) (6) >; Pangalos, Mene (b) (6) >; Pao, William
(b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) >; Paul, Steve <(b) (6) >
Perlmutter, Roger <(b) (6) >; Plenge, Robert (b) (6) >; Plump, Andy
(b) (6) >; Rachel Ramoni <(b) (6) >; Reed, John (b) (6) >; Reese,
David <(b) (6) >; Rouse, Doris <(b) (6) >; Santos, Michael (FNIH) [T] <(b) (6) >
Skovronsky, Daniel (b) (6) >; Stein, Peter (FDA/CDER) <(b) (6) >; Stoffels, Paul
(b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Talley, Michael
(b) (6) >; Tsai, John (b) (6) >; Vessey, Rupert (b) (6) >; Virgin, Skip
(b) (6) >; Wholley, David (FNIH) [T] (b) (6) >; Woodcock, Janet (FDA/CDER)
(b) (6) >; Young, John (b) (6) >; Colvis, Christine (NIH/NCATS) [E]
(b) (6) >; Desrosiers, Betsy (b) (6) >; Eric Hughes
(b) (6) >; Jansen, Kathrin (b) (6) >; Kurilla, Michael (NIH/NCATS) [E]
(b) (6) >; Lowy, Douglas (NCI) (b) (6) >; Read, Sarah (NIH/NIAID) [E] (b) (6)
Young, John (b) (6) >
Cc: Anderson, James (NIH/OD) [E] (b) (6) >; Burklow, John (NIH/OD) [E] (b) (6) >;
Carluccio, Dana (b) (6) >; Castillejos, Carlos <(b) (6) >; FNIH Central Account
(b) (6) >; Gadbois, Ellen (NIH/OD) [E] (b) (6) >; Hallett, Adrienne (NIH/OD) [E]
<(b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E]
(b) (6) >; Tabak, Lawrence (NIH/OD) [E] <(b) (6) >; Wolinetz, Carrie (NIH/OD) [E]

< (b) (6) Gorman, Greta (FNIH) [T] (b) (6) >; Meltzer, Abbey (FNIH) [T]
(b) (6) >; Myles, Renate (NIH/OD) [E] (b) (6) >; Wolinetz, Carrie (NIH/OD) [E]
(b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) >; Margaret Anderson
< (b) (6) >; Appell, Evan (b) (6) Chen, Helen Q. (b) (6) >;
Connelly, Sarah (b) (6) >; Gonzalez, Nina (b) (6) >; Hawk, Harrison
(b) (6) ; Mendelson, Jesse (b) (6) ; Menetski, Joseph (FNIH) [T]
(b) (6) >; Santos, Michael (FNIH) [T] (b) (6) ; asorosa (b) (6) >; Stratton,
Benjamin (b) (6) btolman < (b) (6) ; Tountas, Karen (FNIH) [T]
(b) (6) >; Wachtel, Jonathan (b) (6) ; Wholley, David (FNIH) [T] (b) (6)

Subject: Notes from Thursday's ACTIV Leadership Team Meeting

Dear Leadership Team members and meeting attendees:

Please see the notes from our teleconference this past Thursday, November 19. Please let me know any additional comments, questions, or suggestions regarding these notes or the action items.

Thank you again for all your support of and contributions to ACTIV.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/16/2020 8:32:27 PM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6)]; LaVange, Lisa M [(b) (6)]; Sandeep Menon [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6)]; (b) (6) ; (b) (6) ; (b) (6) ; (b) (6) ; Eron, Joe [(b) (6)]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6)
CC: Demarcus [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Elizabeth Kim [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: ACTIV TX-Clinical Master Protocol Outpatient mAbs Writing Team Meeting #1
Attachments: a5401-d02-051620_hold.docx
Location: https://fnih.zoom.us/ (b) (6)
Start: 5/18/2020 5:00:00 PM
End: 5/18/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; (b) (6) ; (b) (6) ; (b) (6) ; (b) (6) ; (b) (6) ; (b) (6) ; Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; (b) (6)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]

Dear ACTIV-2 Master Protocol Writing Team,

Thank you all for being willing to get together so quickly. I look forward to the ACTIV and the ACTG teams working together to make this protocol great and get it going quickly.

We will work to get a full list of participants and their roles together for this meeting to distribute. In the meantime, the ACTG team has been kind enough to send the current draft of their protocol for us to start from. They have noted to me that they have removed some agent specific information for confidentiality purposes, but all else should be ready for this group to review and start thinking and commenting on.

Thanks,

Stacey

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US (San Jose)

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US (Tacoma)

US (Houston)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

From: LaVange, Lisa M [(b) (6)]
Sent: 4/30/2020 3:18:57 PM
To: 'Levy, Elliott' [(b) (6)]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fda]; Mark Eisner [e (b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6)]; Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6)]
CC: Mary Biggs [(b) (6) DeMarcus, Forrest [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Stratton, Benjamin [(b) (6)]
Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

My concern with the target RRR is whether another agent will be superior to an effective drug to the same extent as remdesivir was to a less effective SoC. Might we need to lower the RRR beyond 1.25?
And these emails highlight why it is probably better to discuss as a group—sorry!
Talk to everyone soon,
Lisa

From: Levy, Elliott [mailto: (b) (6)]
Sent: Thursday, April 30, 2020 10:24 AM

APAR0000005578-2515191

To: LaVange, Lisa M <lisa. (b) (6)> Adam, Stacey (FNIH) [T] < (b) (6)> Bozzette, Sam (NIH/NCATS) [E] < (b) (6)> Butterson, Joan < (b) (6)> Collins, Sylva (FDA/CDER) < (b) (6)> Judy Currier < (b) (6)> De Claro, R. Angelo (FDA/CDER) < (b) (6)> Mark Eisner < (b) (6)> Keith Gottesdiener < (b) (6)> Eric Hughes < (b) (6)> Sandeep Menon < (b) (6)> Amanda Peppercorn < (b) (6)> Proschan, Michael (NIH/NIAID) [E] < (b) (6)> Read, Sarah (NIH/NIAID) [E] < (b) (6)> Amanda Peppercorn < (b) (6)> Price, Dionne (FDA/CDER) < (b) (6)> Rubin, Daniel B. (FDA/CDER) <daniel. (b) (6)> Shen, Yuan Li (FDA/CDER) < (b) (6)> Farley, John (FDA/CDER) < (b) (6)> Goff, David (NIH/NHLBI) [E] < (b) (6)> Vincent, Michael <Michael.Vi (b) (6)>

Cc: Mary Biggs < (b) (6)> DeMarcus, Forrest < (b) (6)> Macone, Erin < (b) (6)> Tountas, Karen (FNIH) [T] < (b) (6)> Wachtel, Jonathan < (b) (6)> Elizabeth Kim < (b) (6)> Parker, Ashley (NIH/OD) [E] < (b) (6)> Butcher, Tina < (b) (6)> Wholley, David (FNIH) [T] < (b) (6)> Melencio, Cheryl (FNIH) [T] < (b) (6)> Wung, Peter /US < (b) (6)> Qashu, Felicia (NIH/OD) [E] < (b) (6)> Stratton, Benjamin < (b) (6)>

Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

I agree that remdesivir will need to become background therapy in all treatment arms. This gives us to opportunity to test regimens which target both the virus and the host, which is exciting.

With regard to the target RRR, in my view the emerging data confirm the need to power for 1.25, rather than something larger:

-Remdesivir (a rationally designed therapy) exhibited an effect of 1.31 in ACCT1 on TTR, and a somewhat smaller effect (1.23) in the terminated Chinese trial. These are our best estimates for what a rationally designed therapy can do.

-In ACCT1, an effect of 1.31 was associated with a reduction in duration of hospital stay by 4 days, which would be meaningful from a health care system perspective.

-I would not expect other therapies we test to exhibit a larger effect than remdesivir. They were not designed to address the pathophysiology of COVID-19, about which we know little, and their benefit might be partially attenuated when used in combination with another active agent.

-A smaller effect for the experimental therapy would still be meaningful, if one could infer the combination of experimental therapy + remdesivir had an effect of 1.5 or more.

Elliott

From: LaVange, Lisa M <(b) (6)>
Sent: Thursday, April 30, 2020 6:50 AM
To: Adam, Stacey (FNIH) [T] <(b) (6)> Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>; Butterson, Joan <(b) (6)> Collins, Sylva (FDA/CDER) <(b) (6)> Judy Currier <(b) (6)> De Claro, R. Angelo (FDA/CDER) <(b) (6)>; Mark Eisner <(b) (6)>; Keith Gottesdiener <(b) (6)>; Eric Hughes <(b) (6)>; Levy, Elliott <(b) (6)>; Sandeep Menon <(b) (6)>; Amanda Peppercorn <(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>; Amanda Peppercorn <(b) (6)> Price, Dionne (FDA/CDER) <(b) (6)>; Rubin, Daniel B. (FDA/CDER) <(b) (6)> Shen, Yuan Li (FDA/CDER) <(b) (6)> Farley, John (FDA/CDER) <(b) (6)> Goff, David (NIH/NHLBI) [E] <(b) (6)>; Vincent, Michael <(b) (6)>

Cc: Mary Biggs <(b) (6)> DeMarcus, Forrest <(b) (6)> Macone, Erin

< (b) (6) : Tountas, Karen (FNIH) [T] < (b) (6) : Wachtel, Jonathan (b) (6) ;
Elizabeth Kim (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) ; Butcher, Tina
(b) (6) >; Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T]
(b) (6) : Wung, Peter /US (b) (6) : Qashu, Felicia (NIH/OD) [E]
(b) (6) >; Stratton, Benjamin < (b) (6)

Subject: [External] Re: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Agree, thanks for raising this, Sam. There are other implications as well. We may need to revisit the meds we will allow as background therapy, now that we have a true standard of care consistent across all sites. And is the target RRR we want to be powered to detect (1.25) the appropriate target relative to Remdesivir?

Looking forward to talking further later today.

Lisa

From: Adam, Stacey (FNIH) [T] < (b) (6)

Sent: Thursday, April 30, 2020 9:44 AM

To: Bozzette, Sam (NIH/NCATS) [E] (b) (6) >; Butterton, Joan (b) (6) >; Collins, Sylva (FDA/CDER) (b) (6) >; Judy Currier (b) (6) >; De Claro, R. Angelo (FDA/CDER) (b) (6) ; Mark Eisner (b) (6) ; Keith Gottesdiener (b) (6) ; Eric Hughes (b) (6) ; LaVange, Lisa M (b) (6) ; Elliott Levy (b) (6) ; Sandeep Menon (b) (6) >; Amanda Peppercorn (b) (6) ; Proschan, Michael (NIH/NIAID) [E] (b) (6) >; Read, Sarah (NIH/NIAID) [E] (b) (6) >; Amanda Peppercorn (b) (6) ; Price, Dionne (FDA/CDER) (b) (6) >; Rubin, Daniel B. (FDA/CDER) (b) (6) >; Shen, Yuan Li (FDA/CDER) (b) (6) ; Farley, John (FDA/CDER) (b) (6) ; Goff, David (NIH/NHLBI) [E] (b) (6) ; Vincent, Michael (b) (6) >

Cc: Mary Biggs (b) (6) ; DeMarcus, Forrest (b) (6) >; Macone, Erin < (b) (6) : Tountas, Karen (FNIH) [T] < (b) (6) : Wachtel, Jonathan (b) (6) ; Elizabeth Kim (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) >; Butcher, Tina (b) (6) >; Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6) >; Wung, Peter /US < (b) (6) : Qashu, Felicia (NIH/OD) [E] (b) (6) >; Stratton, Benjamin (b) (6)

Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Hi Sam,

I think you are correct and we can discuss more today and tomorrow. I am currently trying to figure out what the outreach procedure should be, but I agree it likely needs to sooner rather than later.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Bozzette, Sam (NIH/NCATS) [E] (b) (6)

Sent: Thursday, April 30, 2020 9:19 AM

To: Adam, Stacey (FNIH) [T] (b) (6) ; Butterton, Joan < (b) (6) ; Collins, Sylva

(FDA/CDER) (b) (6) ; Judy Currier (b) (6) De Claro, R. Angelo (FDA/CDER)
 < (b) (6) ; Mark Eisner (b) (6) >; Keith Gottesdiener
 (b) (6) ; Eric Hughes (b) (6) >; LaVange, Lisa M < (b) (6)
 Elliott Levy (b) (6) Sandeep Menon (b) (6) ; Amanda Peppercorn
 (b) (6) >; Proschan, Michael (NIH/NIAID) [E] (b) (6) ; Read, Sarah
 (NIH/NIAID) [E] (b) (6) >; Amanda Peppercorn < (b) (6) Price, Dionne
 (FDA/CDER) < (b) (6) >; Rubin, Daniel B. (FDA/CDER) (b) (6) >; Shen, Yuan Li
 (FDA/CDER) (b) (6) ; Farley, John (FDA/CDER) (b) (6) >; Goff, David (NIH/NHLBI)
 [E] < (b) (6) Vincent, Michael (b) (6)
Cc: Mary Biggs < (b) (6) >; Demarcus (b) (6) >; Macone, Erin (b) (6) >;
 Tountas, Karen (FNIH) [T] (b) (6) ; Wachtel, Jonathan < (b) (6) Elizabeth Kim
 (b) (6) >; Parker, Ashley (NIH/OD) [E] < (b) (6) Butcher, Tina
 (b) (6) ; Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T]
 (b) (6) >; Wung, Peter /US < (b) (6) >; Qashu, Felicia (NIH/OD) [E]
 < (b) (6) Stratton, Benjamin (b) (6)
Subject: Re: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Good morning all:

It would seem that our active control arm had been identified. Should we get in the queue with Gilead sooner rather than later - or have we already reached out to them?

S

From: "Adam, Stacey (FNIH) [T]" (b) (6)
Date: Thursday, April 23, 2020 at 8:31:00 PM
To: "Bozzette, Sam (NIH/NCATS) [E]" < (b) (6) "Butterton, Joan" (b) (6)
 "Collins, Sylva (FDA/CDER)" (b) (6) "Judy Currier" (b) (6) >, "De Claro, R.
 Angelo (FDA/CDER)" (b) (6) >, "Mark Eisner" (b) (6) >, "Keith Gottesdiener"
 < (b) (6) "Eric Hughes" < (b) (6) "LaVange, Lisa M"
 < (b) (6) "Elliott Levy" (b) (6) >, "Sandeep Menon" (b) (6) >,
 "Amanda Peppercorn" (b) (6) >, "Proschan, Michael (NIH/NIAID) [E]"
 (b) (6) , "Read, Sarah (NIH/NIAID) [E]" < (b) (6) "Amanda Peppercorn"
 (b) (6) "Price, Dionne (FDA/CDER)" (b) (6) >, "Rubin, Daniel B.
 (FDA/CDER)" (b) (6) >, "Shen, Yuan Li (FDA/CDER)" (b) (6) >, "Farley, John
 (FDA/CDER)" < (b) (6) "Goff, David (NIH/NHLBI) [E]" < (b) (6) "Vincent, Michael"
 (b) (6) >
Cc: "Mary Biggs" < (b) (6) "Demarcus" (b) (6) >, "Macone, Erin"
 (b) (6) "Tountas, Karen (FNIH) [T]" (b) (6) "Wachtel, Jonathan"
 (b) (6) >, "Elizabeth Kim" (b) (6) "Parker, Ashley (NIH/OD) [E]"
 (b) (6) "Butcher, Tina" (b) (6) "Wholley, David (FNIH) [T]"
 < (b) (6) >, "Melencio, Cheryl (FNIH) [T]" (b) (6) >, "Wung, Peter /US"
 < (b) (6) >, "Qashu, Felicia (NIH/OD) [E]" < (b) (6) "Stratton, Benjamin"
 (b) (6) >
Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for tomorrow's meeting.

1. Agenda
2. Slides for discussion updated with the decisions from today

3. A useful resource about current standard clinical treatment guidelines from the front lines for COVID. This may be a useful resource in selecting how to do minimal data collection and trying to understand SOC.

Please let me know if you have questions or other things you think would be helpful for the group to review.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

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Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: [\(b\) \(6\)](https://fnih.zoom.us/j/(b)(6))

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/21/2020 3:15:54 PM
To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6) .com]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; (b) (6); (b) (6)
Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]
Subject: RE: ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting
Attachments: ACTIV Therapeutics Clinical_Agent Prioritization Sub-Group Meeting Agenda_04192020.pdf; C-19 pipeline by BIO IA 2020-04-19.pdf; 2. Wave 2 Summary_v5[1].xlsx; ACTIVPrioritizationCriteria-v3.xlsx; ACTIV Therapeutics-Clinical_AP Subgroup Meeting 2_21Apr2020 Meeting Guide_v2.pdf

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached updated materials for today's call.

1. Agenda
2. UPDATED - Slides for presentation – Please be sure to take a look at Slide 10 for discussion.
3. Excel spreadsheet of the list the ACCORD team started with for prioritization
4. PDF of assessment that BIO did of their members pipelines for antiviral candidates and list that they came up with for potential use.
5. Updated Prioritization Criteria for the Group's Review and comment. (Excel Spreadsheet)

We look forward to seeing many of you for this discussion.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T]
Sent: Thursday, April 16, 2020 9:29 PM

APAR0000005710-2515192

To: Adam, Stacey (FNIH) [T]; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael
Cc: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) (b) (6)
Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon
Subject: ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting
When: Tuesday, April 21, 2020 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom>. (b) (6)

Dear TX-Clinical Agent Prioritization Subgroup,

Please find attached the materials for tomorrow's call.

1. Agenda
2. Slides for presentation – You will notice that these contain not only our suggested Agent Prioritization Process and Criteria, but also contain the already prioritized list of agents from other groups that have been kind enough to share with us.
3. Excel spreadsheet of the list the ACCORD team started with for prioritization
4. PDF of assessment that BIO did of their members pipelines for antiviral candidates and list that they came up with for potential use.
5. Updated Prioritization Criteria for the Group's Review and comment. (Excel Spreadsheet)

We look forward to seeing many of your for this discussion.

Thanks,

Stacey

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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [(b) (6)]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] (b) (6) ; Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) [(b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [(b) (6) Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6) Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] (b) (6) ; Charette, Marc (NIH/NHLBI) [E] [(b) (6) Fessel, Josh (NIH/NHLBI) [E] [(b) (6) (b) (6) (b) (6) Annaliesa.Anderson@pfizer.com

CC: Wholley, David (FNIH) [T] (b) (6) ; Melencio, Cheryl (FNIH) [T] (b) (6) ; Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Desrosiers, Betsy [(b) (6) Eric Hughes [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6)]; Tountas, Karen (FNIH) [T] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6) Jonson, Samantha (NIH/NCATS) [E] [(b) (6) Gonzalez, Nina [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) antoinette_baric [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) ih.gov]; Florence, Clint (NIH/NIAID) [E] [(b) (6)]; Nancy Haigwood [haigwoon@ohsu.edu]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) .gov]; Anderson, James (NIH/OD) [E] [(b) (6) Hawk, Harrison [(b) (6) Mason, Stephen [(b) (6) (b) (6) Connelly, Sarah [(b) (6) (b) (6) Lumsden, Joanne (NIH/NCATS) [C] (b) (6) ; K C Kent Lloyd [(b) (6) (b) (6) Embry, Alan (NIH/NIAID) [E] [(b) (6) Lerner, Andrea (NIH/NIAID) [E] [(b) (6) Diamond, Michael [(b) (6)]

Start: 5/12/2021 2:00:00 PM
End: 5/12/2021 3:00:00 PM

Recurrence: (none)

From: Tolman, Brett [(b) (6)]
Sent: 12/2/2020 6:28:59 PM
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen];
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dc9f31ded594eff8ac506d2c4103c15-ledgerwood];
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Marks, Peter (FDA/CBER)
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 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Mascola, John
 (NIH/VR) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Nelson Michael
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha];
 kayvon.modjarrad.civ@mail.mil; Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Offit, Paul
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fdb4598a57b423d484dcf9f-offit.email]; Merlin Robb
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6442891c7f7b404486500d6ed251a686-MerlinRobb];
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Laurent Humeau
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 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Parker, Ashley (NIH/OD) [E]
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 [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Martin, Stacey
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 (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Hepburn, Matt (HHS/IOS)
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=322773c4fb274ec5ba1d7c204c58d9f1-MichaelChoy]; Gorman, Richard (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9fa34dbee5794c34b94ee2a55c9dc51e-Richard.Gor]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Buchbinder, Susan (DPH) [(b) (6) mmdavis [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; Tartaglia, Jim /US [(b) (6) (b) (6) Antonio Lanzavecchia [(b) (6)];
Taylor, Kimberly (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40d07049615c454a99400a11c3a9c652-taylorkl]; Follmann, Dean (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=42106b36984344e0914421f5fe408e7b-dfollmann]
CC: (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Sitar, Sandra (NIH/VRC) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e781b1f84a4f878583062a6ae87017-sitars]; Tong, Tina (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Brian Rosen [(b) (6) Cheryl Keech [(b) (6) Sadoff, Jerald [JRDUS] [(b) (6) Michael, Nelson [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=05b9ca6b24634974b7aeb3fcaead1623-nmichael.hi]; Kayvon Modjarrad (b) (6) Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Van Hoof, Johan [JRD BE] [(b) (6) Van Tulden, Karin [JRD BE] (b) (6) (b) (6)
(b) (6) Shannon Devine [(b) (6) Jeneffer Haynes (b) (6) Vivek Shinde [(b) (6) Kathleen Callahan [(b) (6) Brown ScD, Elizabeth R [(b) (6) Lindsey, Nicole (CDC/DDID/NCEZID/DVBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ffab2bf06a684c9ea822683392719418-frd3]; Kublin MD, MPH, James (b) (6) Stoddard, Jeffrey [JRDUS] [(b) (6) David Vaughn [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Mammen Mammen [(b) (6)

Subject: ACTIV Vaccines Clinical Trials Sub-Group Meeting

Location: <https://deloitte.zoom.us> (b) (6)

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End: 12/18/2020 7:00:00 PM

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Recurrence: (none)



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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/13/2020 2:37:49 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [amanda.f. (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6) Karen Lynn Price [(b) (6) Pamela Tenaerts, M.D. [(b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [(b) (6) Beumont-Mauviel, Maria [JRDUS] [(b) (6) .com]; Peeters, Monika [JRDBE] [(b) (6) Woodfall, Brian [JRDUS] [(b) (6) Van Heeswijk, Rolf [JRDBE] [(b) (6)
CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Materials for ACTIV TX-Clinical Master Protocol Subgroup Meeting #16
Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_13May2020 Meeting Guide.pdf

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the slides for our portion of the meeting tomorrow. The presentation slides from I-SPY will be shared on the call from their group.

We are going to try to keep the I-SPY presentation to no more than 40 minutes, including questions so we can discuss a few necessary matters for next steps on our trials.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

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US (San Jose)

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US (Houston)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/u> (b) (6)

From: Proschan, Michael (NIH/NIAID) [E] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=7B45059209B4468BB4BA02B0DFBBB3E4-PROSCHAM]
Sent: 4/29/2020 5:34:33 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Has ACTT1 been stopped?

The trial has accrued its target number of patients and recoveries, so this is not really an "interim" result. The DSMB recommended releasing the data to the NIH, and Dr. Fauci just announced preliminary results today. Follow up of all patients to at least 28 days will continue, but results will not change appreciably. Remdesivir was statistically significantly superior to placebo in terms of the primary endpoint, time to recovery. More detailed results will be coming soon.

Mike

From: Adam, Stacey (FNIH) [T] < (b) (6) >
Sent: Wednesday, April 29, 2020 1:27 PM
To: Bozzette, Sam (NIH/NCATS) [E] < (b) (6) > Butterson, Joan < (b) (6) > Collins, Sylva (FDA/CDER) < (b) (6) > Judy Currier < (b) (6) > De Claro, R. Angelo

(FDA/CDER) < (b) (6) Mark Eisner < (b) (6) Keith Gottesdiener
< (b) (6) Eric Hughes < (b) (6) LaVange, Lisa M < (b) (6)
Elliott Levy < (b) (6) Sandeep Menon < (b) (6) Amanda Peppercorn
< (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah
(NIH/NIAID) [E] < (b) (6) Amanda Peppercorn < (b) (6) Price, Dionne
(FDA/CDER) < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) Shen, Yuan Li
(FDA/CDER) < (b) (6) Farley, John (FDA/CDER) < (b) (6) Goff, David (NIH/NHLBI)
[E] < (b) (6) Vincent, Michael < (b) (6) Wung, Peter /US
<Peter. (b) (6)
Cc: Mary Biggs < (b) (6) Demarcus < (b) (6) Macone, Erin < (b) (6)
Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan < (b) (6) Elizabeth Kim
< (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Butcher, Tina
< (b) (6) Wholley, David (FNIH) [T] < (b) (6) Melencio, Cheryl (FNIH) [T]
< (b) (6)

Subject: RE: Has ACTT1 been stopped?

Hi Sam,

DSMB was this week to review interim results, though the trial has fully accrued, so the interim may quickly transition to final. However, we were only expecting some blinded results to point us in the right direction next week. I will let Michael or others weigh in if my understanding was in correct.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Bozzette, Sam (NIH/NCATS) [E] < (b) (6) >
Sent: Wednesday, April 29, 2020 1:22 PM
To: Adam, Stacey (FNIH) [T] < (b) (6) > Butterson, Joan < (b) (6) > Collins, Sylva
(FDA/CDER) < (b) (6) > Judy Currier < (b) (6) > De Claro, R. Angelo (FDA/CDER)
< (b) (6) > Mark Eisner < (b) (6) > Keith Gottesdiener
< (b) (6) > Eric Hughes < (b) (6) > LaVange, Lisa M < (b) (6) >
Elliott Levy < (b) (6) > Sandeep Menon < (b) (6) > Amanda Peppercorn
< (b) (6) > Proschan, Michael (NIH/NIAID) [E] < (b) (6) > Read, Sarah
(NIH/NIAID) [E] < (b) (6) > Amanda Peppercorn < (b) (6) > Price, Dionne
(FDA/CDER) < (b) (6) > Rubin, Daniel B. (FDA/CDER) < (b) (6) > Shen, Yuan Li
(FDA/CDER) < (b) (6) > Farley, John (FDA/CDER) < (b) (6) > Goff, David (NIH/NHLBI)
[E] < (b) (6) > Vincent, Michael < (b) (6) > Wung, Peter /US
< (b) (6) >
Cc: Mary Biggs < (b) (6) > Demarcus < (b) (6) > Macone, Erin < (b) (6) >
Tountas, Karen (FNIH) [T] < (b) (6) > Wachtel, Jonathan < (b) (6) > Elizabeth Kim
< (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) > Butcher, Tina
< (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Melencio, Cheryl (FNIH) [T]
< (b) (6) >

Subject: Has ACTT1 been stopped?

<https://www.cnn.com/2020/04/29/dr-anthony-fauci-says-data-from-remdesivir-coronavirus-drug-trial-shows-quite-good-news.html>

From: Bozzette, Sam (NIH/NCATS) [E]

Sent: Wednesday, April 29, 2020 9:19 AM

To: Adam, Stacey (FNIH) [T] <(b) (6)> Butterson, Joan (b) (6) Collins, Sylva (FDA/CDER) <(b) (6)> Judy Currier <(b) (6)> De Claro, R. Angelo (FDA/CDER) <(b) (6)> Mark Eisner <(b) (6)> Keith Gottesdiener <(b) (6)> Eric Hughes <(b) (6)> LaVange, Lisa M <(b) (6)> Elliott Levy <(b) (6)> Sandeep Menon <(b) (6)> Amanda Peppercorn <(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Amanda Peppercorn <(b) (6)> Price, Dionne (FDA/CDER) <(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)> Shen, Yuan Li (FDA/CDER) <(b) (6)> Farley, John (FDA/CDER) <(b) (6)> Goff, David (NIH/NHLBI) [E] <(b) (6)> Vincent, Michael <(b) (6)> Wung, Peter /US <(b) (6)>

Cc: Mary Biggs <(b) (6)> Demarcus <(b) (6)> Macone, Erin <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)> Elizabeth Kim <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Butcher, Tina <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)>

Subject: Of interest re remdesivir

https://www.statnews.com/2020/04/29/gilead-says-critical-study-of-covid-19-drug-shows-patients-are-responding-to-treatment/?utm_source=STAT+Newsletters&utm_campaign=f9a2a59829-breaking_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-f9a2a59829-152058113

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] <(b) (6)>

Sent: Wednesday, April 29, 2020 2:44 AM

To: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; LaVange, Lisa M; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US

Cc: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Subject: Canceled: ACTIV TX-Clinical Master Protocol Subgroup Meeting #11

When: Wednesday, April 29, 2020 3:00 PM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us> (b) (6)

Importance: High

Dear TX-Clinical Master Protocol Subgroup,

The co-chairs and subgroup chair have decided that the best use of the group's time is to hold off and reconvene with CTC WG at 12pm ET on Thursday and as our team on Friday. For Thursday, you should have an invite from Karent Tountas for the meeting with the CTC group.

See you all Thursday!

Stacey

APAR0000005625-2515198

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Password: (b) (6)

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US (San Jose)

US (San Jose)

US

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/u> (b) (6)

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 2/18/2021 6:49:59 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Gonzalez, Nina [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx
Attachments: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

War room colleagues:

As I mentioned on yesterday morning's call, the group within the ACTIV Therapeutics Clinical working group that has been considering what structures NIH might consider to prioritize the use of surplus biosamples from across the ACTIV trials has reached a point in their deliberations where they felt it would be a good idea check in with leadership on what they are planning to bring forward in the way of recommendations. We agreed it would be a good idea to have Stacey Adam join war room and discuss this for ~10 minutes during one of our regularly scheduled morning meetings. It turns out that this coming Monday 2/22 at 8AM works best for Stacey's calendar. Please let me know if this is a good time slot. The slides are attached here for your advance review.

Thanks,
David

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 6/1/2020 5:04:26 PM
To: (b) (6); (b) (6); (b) (6); (b) (6)
Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; (b) (6)
(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) [(b) (6) Bett, Andrew J [(b) (6) Gilbert PhD, Peter B [(b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA) [(b) (6) Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Greg Glenn [(b) (6) Cavaleri Marco [(b) (6)
CC: Tolman, Brett [(b) (6)]; (b) (6); (b) (6)
(b) (6) Jeneffer Haynes [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Brian Rosen [(b) (6) Cheryl Keech [(b) (6)
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting tomorrow (Tuesday)
Attachments: M_Cavaleri_regulatory_framework_emergencies.ppt; Pathways for Vaccine Use or Approval in the US Slides-May 21-clean.pptx

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting tomorrow (Tuesday) at 8am ET (5am PT / 2pm CEST). We are very sorry for the extremely early start PT.

The main agenda item is to discuss EMA and member state regulatory pathways to vaccine use and approval. Marco will lead the discussion. He previously shared a set of presentation slides (re-attached here). We are also re-attaching the table on FDA pathways that we circulated previously.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Thursday, May 28, 2020 12:57 PM
Subject: Notes and next steps from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting. Notes are attached.

There were two key areas for next steps that we identified in the meeting:

- Potential signals of human immunity:
 - Develop specifics of what we are looking for from immunology research
 - Ask the WG and other contacts for suggestions of researchers/organizations worth reaching out to
 - Reach out and collect information and contacts to engage with the WG (in presentations or other formats)
- Inter-comparability of immunogenicity assays / centralized labs
 - Reach out to NIAID to learn more about planned centralized lab capabilities and timing

Ann kindly followed up with an initial set of recommendations for the first area. We'll be following up to develop the list of information that we'd like to gather and to discuss how to prioritize whom we reach out to. We'll reach out to NIAID and report back on the second area.

We think these topics will form the basis for future discussions, but we are also trying to schedule a meeting for a time when we can have a discussion about the EMA regulatory pathways with Marco, to complement the conversations we have had on FDA pathways. We hope to have an invite for that out soon.

As always, please reach out with any additional input on the notes, questions, or suggestions for future directions for this group.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Tuesday, May 26, 2020 11:42 PM

Subject: Agenda for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Tuesday, May 26, 2020 12:19 AM

Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Tuesday, May 19, 2020 8:56 AM

Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

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APAR0000006184-2515201

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 7/23/2020 9:57:23 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: FW: A problem participating in next week's leadership group meeting

FYI, this will be reflected in the agenda. Am starting to get requests from IC Directors to attend. Cheryl can batch up the names of those we've heard from, say Monday?, and send to you all. David

From: Wholley, David (FNIH) [T]
Sent: Thursday, July 23, 2020 5:47 PM
To: Lowy, Douglas (NIH/NCI) [E] <(b) (6)>
Cc: Santos, Michael (FNIH) [T] <(b) (6)> Tolman, Brett <(b) (6)>
Subject: RE: A problem participating in next week's leadership group meeting

Certainly Doug. Ras oncogene is a big deal! I will slate you to go first among the groups and notify the necessary parties. David

From: Lowy, Douglas (NIH/NCI) [E] <(b) (6)>
Sent: Thursday, July 23, 2020 5:41 PM
To: Wholley, David (FNIH) [T] <(b) (6)>
Cc: Santos, Michael (FNIH) [T] <(b) (6)>; Tolman, Brett <(b) (6)>
Subject: A problem participating in next week's leadership group meeting
Importance: High

David,

Please accept my apologies, but I have just realized that I need either to participate only in the first 25 minutes of the July 29 ACTIV Leadership group meeting or miss it entirely. Kathrin has indicated she will probably be unable to attend. You might want to consider having the vaccine working group be the first of the four groups to present.

(FYI: I am participating in a two day research meeting about the RAS oncogene that begins July 29, 11 AM to 4:30 PM. More than 1,000 people have registered for the meeting [who knew there were that many people who were interested in something other than COVID-19?]. I can break away from the meeting between 3 PM and 3:25 but need to get back to it by 3:30, as I am participating in that part of the program. <https://www.eventbrite.com/e/frank-mccormick-racing-to-bridge-the-gaps-ras-pathway-signaling-in-cancer-tickets-110321522644>)

Thanks for your understanding,
Doug

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGE LABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/22/2020 1:00:37 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [(b) (6)
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #5
Location: https://fnih.zoom.us/j/ (b) (6)
Start: 4/22/2020 6:00:00 PM
End: 4/22/2020 7:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US

Stacey Adam is inviting you to a scheduled Zoom meeting.

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